COMPARISON OF CLINICAL PERFORMANCE OF TWO SUPRAGLOTTIC AIRWAY DEVICES, I-GEL WITH PROSEAL - LARYNGEAL MASK AIRWAY (LMA) IN PATIENTS UNDERGOING ELECTIVE SURGERIES – A PROSPECTIVE RANDOMIZED STUDY

Dissertation submitted to

THE TAMILNADU DR.M.G.R MEDICAL UNIVERSITY

In partial fulfilment for the award of the degree of

DOCTOR OF MEDICINE

IN

ANAESTHESIOLOGY

BRANCH X

DEPARTMENT OF ANAESTHESIOLOGY,

THANJAVUR MEDICAL COLLEGE,

THANJAVUR – 613004.

MAY 2018

CERTIFICATE

This is to certify that the dissertation entitled **"COMPARISON OF CLINICAL PERFORMANCE OF TWO SUPRAGLOTTIC AIRWAY DEVICES, I-GEL WITH PROSEAL - LARYNGEAL MASK AIRWAY (LMA) IN PATIENTS UNDERGOING ELECTIVE SURGERIES – A PROSPECTIVE RANDOMIZED STUDY "** submitted by **Dr.T.SATHIYA** in partial fulfilment for the award of the degree of **Doctor of Medicine in Anaesthesiology** by the Tamilnadu Dr.M.G.R Medical University,Chennai is a bonafide record of the work done by her in the Department of Anaesthesiology, Government Thanjavur Medical College ,during the academic year 2014 – 2018.

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Approval No. : 391

This is to certify that The Research Proposal / Project titled

COMPARISON OF CLINICAL PERFORMANCE OF TWO SUPRAGLOTTIC AIRWAY DEVICES, I-GEL WITH PROSEAL LMA IN PATIENTS UNDERGOING ELECTIVE SURGERIES- A PROSPECTIVE, RANDOMIZED STUDY

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was approved by the Ethical Committee.

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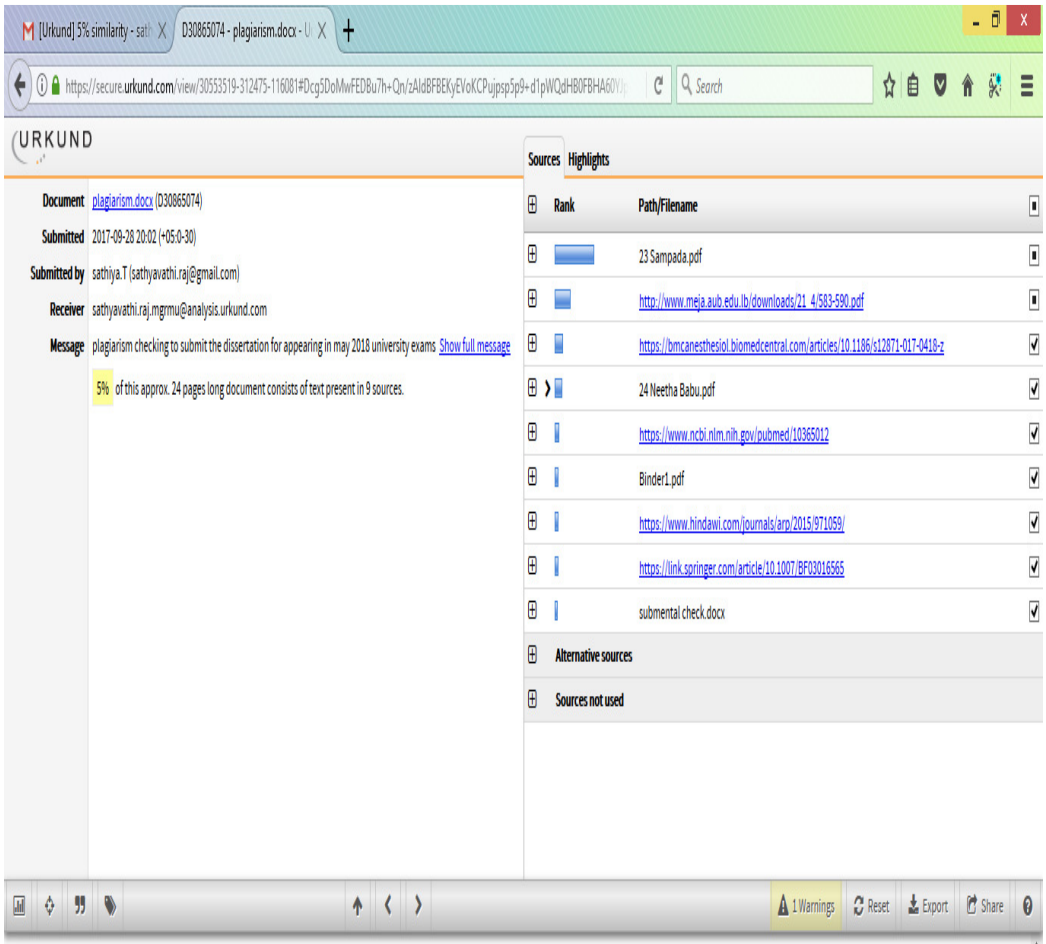

INTRODUCTION

"Securing the airway during conduction of general anaesthesia", is one of the most important jobs of the anaesthesiologist. Ventilation during anaesthesia was managed without specialized airway devices for more than 50 years after Morton's discovery. Friedrich Von Esmarch, described 'the jaw thrust as a lifesaving maneuver' in some cases of airway obstruction that resulted from chloroform or asphyxia. The development of the modern facemask originated with Francis Sibson who devised a mask made of pliable tinned iron covered with glove leather. The mask covered the mouth and nose and therefore eliminated the need for nose clips.1

CERTIFICATE - II

This is to certify that this dissertation work titled **"COMPARISON OF CLINICAL PERFORMANCE OF TWO SUPRAGLOTTIC AIRWAY DEVICES, I-GEL WITH PROSEAL - LARYNGEAL MASK AIRWAY (LMA) IN PATIENTS UNDERGOING ELECTIVE SURGERIES – A PROSPECTIVE RANDOMIZED STUDY"** of the candidate **Dr.T.SATHIYA** with registration Number **201420205** for the award of **DOCTOR OF MEDICINE** in the branch of **ANAESTHESIOLOGY (BRANCH X).** I personally verified the urkund.com website for the purpose of plagiarism Check. I found that the uploaded thesis file contains from introduction to conclusion pages and result shows **5** percentage of plagiarism in the dissertation.

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DECLARATION

I, **Dr.T.SATHIYA** solemnly declare that the dissertation titled **"COMPARISON OF CLINICAL PERFORMANCE OF TWO SUPRAGLOTTIC AIRWAY DEVICES, I-GEL WITH PROSEAL - LARYNGEAL MASK AIRWAY (LMA) IN PATIENTS UNDERGOING ELECTIVE SURGERIES – A PROSPECTIVE RANDOMIZED STUDY"** is a bonafide work done by me at Thanjavur Medical College Hospital , Thanjavur , during 2015 – 2018.

The dissertation is submitted to **"The Tamilnadu Dr.M.G.R Medical University,Chennai"** Tamilnadu as a partial fulfilment for the requirement of M.D Degree examinations – Branch –X(Anaesthesiology) to be held in May 2018.

Place: Thanjavur

Date: **Dr.T.SATHIYA**

INDEX

INTRODUCTION

Securing the airway during conduction of general anaesthesia is one of the most important jobs of the anaesthesiologist. Ventilation during anaesthesia was managed without specialized airway devices for more than 50 years after Morton's discovery. Friedrich Von Esmarch described the jaw thrust as a lifesaving maneuver in some cases of airway obstruction that resulted from chloroform or asphyxia. The development of the modern facemask originated with Francis Sibson who devised a mask made of pliable tinned iron covered with glove leather. The mask covered the mouth and nose and therefore eliminated the need for nose clips.[1]

In the 18th century, tubes were passed into the trachea during resuscitation from drowning, but these tubes were passed without direct visualization and were not meant for the delivery of anaesthetic agents. Sir William Macewen was the first physician to intubate the trachea orally for the sole purpose of administering anaesthesia. Robert R. Macintosh's improved laryngoscope featured a short, curved blade that elevated instead of retracting the epiglottis, a considerable improvement over previous laryngoscopes[2]. Laryngoscopy and endotracheal intubation is a common method of securing the airway. However intubation is associated with tachycardia and hypertension, which is transient. A change in plasma catecholamine concentrations also has been seen[3]. Transitory hypertension and tachycardia are probably of no consequence in healthy individuals but either or both may be hazardous to those with hypertension, myocardial insufficiency or cerebrovascular diseases.[4]

In the year 1983, Dr.Archie Brain described a new type of airway, which may be used as an alternative to the endotracheal tube or the facemask with either spontaneous or positive pressure ventilation. This was the Laryngeal Mask Airway (LMA). It was introduced into clinical practice in 1988. Since its introduction it has undergone many modifications and addition of various new models[5]. The wide variety of airway devices available today may broadly be classified as cuffed perilaryngeal sealers, and cuffless anatomically pre shaped sealers based on their sealing mechanisms[6]. As time went on, additional devices were added to the LMA family to satisfy specific needs and a number of other devices were developed. There are a large number of supraglottic airway devices, some of which appear similar to the LMA family and others that work under a different concept[7]. Originally intended as an alternative to mask ventilation, the supraglottic airway devices avoid many problems associated with intubation[8,9]. The popularity of the device for routine use stems from its perceived benefits to the patient and anaesthetist over traditional forms of airway management[10].

Laryngeal mask airway is a supraglottic airway device with an inflatable cuff forming a low pressure seal around the laryngeal inlet and permitting ventilation. The primary limitation of the laryngeal mask airway (LMA) is that it does not reliably protect the lungs from regurgitated stomach contents, although it may act as a barrier at the level of the upper esophageal sphincter if it is correctly positioned. The incidence of aspiration with the LMA has been estimated at 0.02%, which is similar to tracheal intubation in elective patients.[11]

Proseal laryngeal mask airway, a supraglottic airway device with an inflatable cuff and gastric drain tube has been widely used in paediatric and adult patients under both controlled and spontaneous ventilation[12,13,14].The I-gel is a relatively newer and unique single use supraglottic airway device with non-inflatable cuff that snugly fits onto the perilaryngeal framework and has a gastric drain tube[15,16]. I-gel has been successfully used in both spontaneous and controlled ventilation.[17,18]

In view of this, the present study was undertaken in Thanjavur medical college, Thanjavur to compare the performance of two supraglottic airway devices, I-gel and proseal laryngeal mask airway (LMA) in relation to the time taken for insertion, number of attempts taken to insert the device, airway sealing pressure, ease of gastric tube placement, hemodynamic changes after insertion and post-operative complications in patients posted for puerperal/laparoscopic sterilisation under general anaesthesia.

AIM AND OBJECTIVES OF THE STUDY

AIM OF THE STUDY:

To study and compare I-gel and proseal laryngeal mask airway as a supraglottic airway device in patients undergoing elective surgeries.

PRIMARY OBJECTIVE:

To compare 1. The time taken for insertion.

2. Number of attempts taken to insert the device.

3. Airway sealing pressure.

4. Ease of gastric tube placement.

5. Hemodynamic changes after insertion.

SECONDARY OBJECTIVE:

To compare - Adverse effects such as post extubation cough,laryngospasm, nausea/vomiting, trauma to lip/teeth/pharynx and post operative sore throat.

REVIEW OF LITERATURE

Goyal R et al had done a prospective randomized study, published in 2011, in 120 children who underwent elective surgery of less than one hour duration, comparing size 2 Classic LMA, P-LMA and I-gel. This study was conducted at the Armed Forces Medical College, involved children of age two to five years, without anticipated airway difficulties and ASA I and II.The insertion ease and oro-pharyngeal sealing pressure had been compared. The authors had found that I-gel insertion was easy and the oro-pharyngeal sealing pressure was also found to be higher than the other two devices. The oro-pharyngeal sealing pressure of I-gel was found to be (26 ± 2.6 cm H_2O) as compared to that of P-LMA (23 ± 1.2cm H_2O) and Classic LMA (22± 2.3 cm H_2O) which was statistically significant. The authors concluded that I-gel could be used as a safe alternative to the LMA for day care surgeries.[13]

Levitan RM et al published a study in 2005, that studied the positioning and mechanics of I-gel, an anatomically designed mask made of gel like thermoplastic elastomer, without an inflatable cuff. They found the mean percentage of glottis opening score for 73 insertions was 82% (95% confidence interval 75-89%). They found that I-gel effectively conformed to perilaryngeal anatomy and consistently achieved proper positioning for supraglottic ventilation.[15]

Sai S et al compared the efficacy of I-gel with P-LMA in paediatric patients under general anesthesia with controlled ventilation. A total of 60 patients of ASA I, II were included. Insertion parameters, ease of gastric tube insertion, fiberoptic scoring of glottis, airway parameters ($EtCO_2$ and airway pressures),complications in first 12 hours postoperatively were noted. They found both groups were comparable in all the parameters. There were no significant complications in first 12 hours. They concluded that I-gel was effective as P-LMA in paediatric patients under controlled ventilation.[19]

Gurudas K et al compared I-gel with P-LMA in 48 adults of ASA I, II between age 18 and 60 years, undergoing elective surgery under general anesthesia without paralysis. They compared time taken for insertion, effective seal, fiberoptic view of larynx, ease of ryle's tube insertion and postoperative sore throat. They found lesser insertion time with I-gel (21.98± 5.42 secs) compared to P-LMA (30.60 ± 8.51 secs). The number of insertion attempts, fiberoptic view, and ease of ryle's tube insertion and incidence of complication were comparable.[20]

Anjan D et al had compared I-gel with P-LMA in 60 adult ASA I, II between age 20 and 30 yrs of either sex. They compared the hemodynamic alterations in heart rate and blood pressure caused by the stress response by the devices. They found I-gel was more easy to insert (90% vs. 83.33%) and insertion time was shorter (14.9 vs. 20 secs) compared to P-LMA. They also found hemodynamics was lesser altered with I-gel than P-LMA, which were statistically significant.[21]

Gaurav C et al had compared I-gel with P-LMA in 80 adult ASAI, II between age 18 and 65 yrs of either sex. Insertion parameters, ease of gastric tube insertion, fiber-optic assessment, airway sealing pressures, and other complications were compared. They found mean insertion time less in I-gel (11.12± 1.814 secs) compared to P-LMA (15.13 ± 2.91 secs). The mean airway sealing pressure in the P-LMA group (29.55 ± 3.53 cms H_2O) was significantly higher than in the I-gel group (26.73 ± 2.52 cm H_2O). Also gastric tube insertion was easier in I-gel (p =0.001). Complications were less with I-gel compared to P-LMA.[22]

Shi YB et al compared the efficacy of LMA supreme, proseal LMA and I-gel in patients undergoing laparoscopic surgery and found airway sealing pressure were higher in P-LMA and I-gel compared to supreme LMA. They also stated that I gel provided adequate ventilation during surgery with lesser complications.[23]

Hayashi K et al compared single use I-gel with reusable P-LMA in spontaneously breathing adult patients. They found I-gel had faster insertion time (4.4 vs.16 secs, P <0.01) and did not require finger insertion with the device. Leak pressure was found to be similar in both the groups.[24]

Gasteiger L et al had compared size 2 P-LMA and I-gel in a randomized crossover study published in 2012. This study was conducted in 51 children who were not paralysed but maintained with Remifentanyl, Propofol mixture and ventilated. The children were between 1.5 and 6 years of age and weighed 10 to 25 kg. The oro-

pharyngeal sealing pressures were 22 cmH_2O for P-LMA and 21cmH_2O for I-gel. The authors reported similar oro-pharyngeal sealing pressure and fibreoptic view for both devices.[25]

Subro M et al had conducted a study, published in 2012, comparing I-gel and P-LMA of 2.5 sizes in children. The 60 subjects were paralysed and undergoing elective surgery under ASA I, II. The authors had found demographic data, insertion ease, hemodynamics and complications to be comparable. This randomized, prospective study reports a higher airway-leak pressure for I-gel(27.12±1.69 cmH_2O) which was statistically significant when compared to that of P-LMA (22.75±1.46) cm H_2O, concluding that the oro-pharyngeal sealing pressure is the only parameter higher in I-gel.[26]

Van Zundert TC et al had studied I-gel, P-LMA and LMA supreme in 150 patients, belonging to ASA I and II, between the ages of 18 to 60 years. This study was published in 2012. A laryngoscope guided, gastric tube guided technique had been used by the authors for insertion of the devices studied. They had reported easier and shorter time requirement for insertion of both P-LMA and I-gel. The anatomical positioning was found to be better with LMA supreme. The authors reported similar oro-pharyngeal sealing pressures with all the three devices in both apnoeic and spontaneously breathing conditions.[27]

Woo JJ et al had published in 2012, a study conducted in 30 adult patients undergoing laparoscopic gynaecological surgeries; prospectively, randomly assigned to two groups P-LMA and I-gel. The time taken for insertion and the number of attempts required were compared along with measurement of airway-leak pressure.

The airway-leak pressures measured 10 minutes after insertion are reported to be (25.9 ± 5.2 cmH_2O) for P-LMA and (24.3 ± 3.4 cmH_2O) for I-gel. After 15 minutes of CO2 insufflation, the airway-leak pressures were (28.3 ± 5.9) cmH_2O and (28.5 ± 5.4) cmH_2O, respectively. There was no statistically significant difference between the two devices regarding the above mentioned parameters.[28]

Amr M et al in a study published in 2010, had compared I-gel and Classic LMA in 80 non paralysed patients of age 21 to 60 years,body mass index 20-25kg/m^2, undergoing surgeries in supine position for not more than two hours. In this prospective randomized trial, the authors had studied the duration and number of attempts of insertion, gastric insufflations incidence, leak pressure and assessment of the airway after removing the device. A significantly short duration taken for insertion of I-gel (15.6 ± 17.7 seconds) as opposed to that of classic LMA (26.2 ± 17.7 seconds) has been reported. Leak pressure was (25.6 ± 4.9 cm H_2O) vs. (21.2 ± 7.7 cm H_2O) significantly higher in I-gel (P=0.016) and incidence of gastric insufflation was significantly more with classic LMA (22.5%) as compared to I-gel (5%) (P=0.016). All other parameters compared were similar.[29]

Gasteiger L et al in 2010 published a randomized, non-crossover study in 152 female patients between 18 and 70 years. They tested the ease of insertion using a duodenal tube guided insertion and the oro-pharyngeal leak pressure between P-LMA and I-gel. They found overall insertion rate, mean insertion attempts were similar in both the groups. Mean oro-pharyngeal leak pressure was higher in P-LMA group. They concluded that insertion of both the devices were similarly easy using a guided technique and P-LMA forms an effective seal for ventilation.[30]

Singh I et al had published a study in 2009. They had compared P-LMA and I-gel in a population of 60 ASA I, II adult patients undergoing elective surgery. In this prospective randomized study airway-leak pressure,ease of insertion, ease of insertion of orogastric tube and complications like trauma to the airway-lips, teeth and blood staining after removal were noted. The airway-leak pressure for I-gel was a mean of 25.27 cm H_2O and that with PLMA was a mean of 29.6 cm H_2O. The airway sealing pressure of I-gel was very well within normal limits to prevent aspiration. The ease of' insertion was more with I-gel (29/30) than with P-LMA (23/30). Whereas, incidence of airway trauma and blood staining were not statistically different.[31]

Lardner R et al had published a randomized comparative study in 2008, comparing size 2 P-LMA and Classic LMA in paralysed, ventilated children. 51 children of weight 10 to 20 kg within ASA I, II were studied. The oro-pharyngel leak pressure for P-LMA (23.7cmH_2O) was significantly higher than that of classic LMA(16.5cmH_2O). Leak fraction values were similar for both devices. Fiberoptic view was better for P-LMA. Gastric insufflations was more common during leak determination in case of Classic LMA (12/26 Classic LMA and 2/25 P-LMA,p-0.006).[32]

Goldman K et al published a study in 2005, comparing size 2 Classic LMA and P-LMA in 30 spontaneously breathing children of weight 10 to 21 kg. The variables in this randomized crossover study were insertion ease, initial airway quality,fiberoptic position, maximum tidal volume and airway-leak pressure. The authors had reported a significantly high maximum tidal volume and airway-leak for P-LMA (p value

0.001). The insertion ease and initial airway quality were observed to be similar. The authors concluded that the above mentioned advantages of P-LMA could have implications for using the device for positive pressure ventilation in children.[33]

Shimbori Het al had published a study in 2004, in 60 patients belonging to ASA I, II of age 1-6 years and weight 10-20 kg, who underwent herniorrhaphy, myringotomy and orchidopexy. The authors had compared Classic LMA and P-LMA. They found the ease of insertion and airway-sealing pressure to be similar for the two LMAs. They also found no difference in the anatomical positions as determined by fiberoptic bronchoscopy.[34]

Figueredo E et al had published a randomized study in 2003 between P-LMA and laryngeal tube by considering ease of insertion, hemodynamic changes and ventilation qualities in spontaneously breathing,anaesthetized,adult ASA I, II patients. They found first time insertion success rates were high with P-LMA (77% vs. 51%). Expired tidal volume and ability to achieve hands-free ventilation were high with P-LMA. They concluded that P-LMA showed greater ease of insertion and reliability than laryngeal tube.[35]

Brimacombe J et al in 2002 published a multicenter study comparing P-LMA with classic LMA. They compared insertion success rate and time, efficacy of seal, fiberoptically determined anatomic position, oro-gastric tube success, intra operative and post operative complications. About 384 adult patients of ASA I, II was taken into study. Based on this study they concluded that insertion was easier in classic LMA and P-LMA formed better seal and allowed easier and quicker insertion of oro-

gastric tube. Intra operative complications and postoperative sore throat were similar in both the groups.[36]

Brimacombe J et al published 'The Proseal Laryngeal Mask Airway'- a randomized, crossover study in 2000 with standard LMA in 60 adult paralysed patients and found P-LMA was capable of achieving a more effective seal than the LMA and facilitated gastric tube placement. At the same time, P-LMA was more difficult to insert unless an introducer tool was used.[37]

Brain AIJ et al published in 2000 studied about Proseal LMA- a laryngeal mask with esophageal vent. Their crossover comparison with classic LMA in 30 adult female patients showed no difference in insertion, trauma or airway quality. At 60 cms H_2O intra cuff pressure, the P-LMA gave twice the sealing pressure of classic LMA. ($p < 0.0001$) and permitted blind insertion of gastric tube in all cases.[38]

Keller C et al in 1999, compared four tests for comparing airway sealing pressure with LMA-the audible noise, oral capnography, manometric stability and auscultation methods. They studied 80 anaesthetized, paralysed adult patients. They concluded manometric stability test had higher mean airway sealing pressure ($p < 0.0001$) and better inter-observer reliability ($p < 0.0001$) compared to other tests.[39]

ANATOMY OF UPPER AIRWAY

PHARYNX:

The pharynx extends from posterior aspect of the nose at the base of the skull down to the level of lower border of cricoid cartilage where it becomes continuous with oesophagus, and the respiratory tract through larynx. The soft palate partially divides the pharynx into two, an upper nasopharyngeal portion and a lower oropharyngeal portion. Pharynx is partially divided by the soft palate into

1) Nasopharynx,

2) Oropharynx,

3) Laryngopharynx.

1)**Nasopharynx:**

This is upper part of pharynx situated behind the nose, and above the lower border of soft palate. The roof and posterior wall form a continuous slope, opposite the posterior part of body of sphenoid, basiocciput and anterior arch of atlas. Under the mucous membrane, opposite the basiocciput is a collection of lymphoid tissue called nasopharyngeal tonsil or adenoids.

2)**Oropharynx:**

It is the middle part of pharynx, starts below the soft palate and extends to hyoid bone to continue as laryngopharynx at the level of upper border of the epiglottis.

Behind, it is supported by the body of the axis vertebra. In the lateral walls of oropharynx are situated the tonsillar pillars or fauces. The anterior pillar contains glossopharyngeal muscle and the posterior pillar contains palatoglossus muscle.

3) Laryngopharynx:

It is also called hypopharynx. It is situated behind the larynx. It extends from upper border of the epiglottis to lower border of the cricoid cartilage. The lateral wall presents a depression called piriform fossa, one on each side of the inlet of larynx. The fossa is bounded medially by aryepiglottic fold and laterally by thyroid cartilage and thyrohyoid membrane. Beneath the mucosa of the fossa, there lies the internal laryngeal nerve. Removal of the foreign bodies from the piriform fossa may damage this nerve.

TONGUE:

Tongue is a muscular organ situated in the floor of the mouth. It has an oral part that lies in the mouth and a pharyngeal part that lies in the pharynx. The oral and pharyngeal parts are separated by a V shaped sulcus, the sulcus terminalis.

Oral part: Placed on the floor of the mouth. The margins are free and in contact with gums and teeth.

Pharyngeal part: The posterior part of the tongue is connected to epiglottis by folds of mucous membrane. These are median glossoepiglottic fold and the right and left glossoepiglottic folds. On either side of the median fold there is a pouch called vallecula. The lateral folds separate the vallecula from piriform fossa.

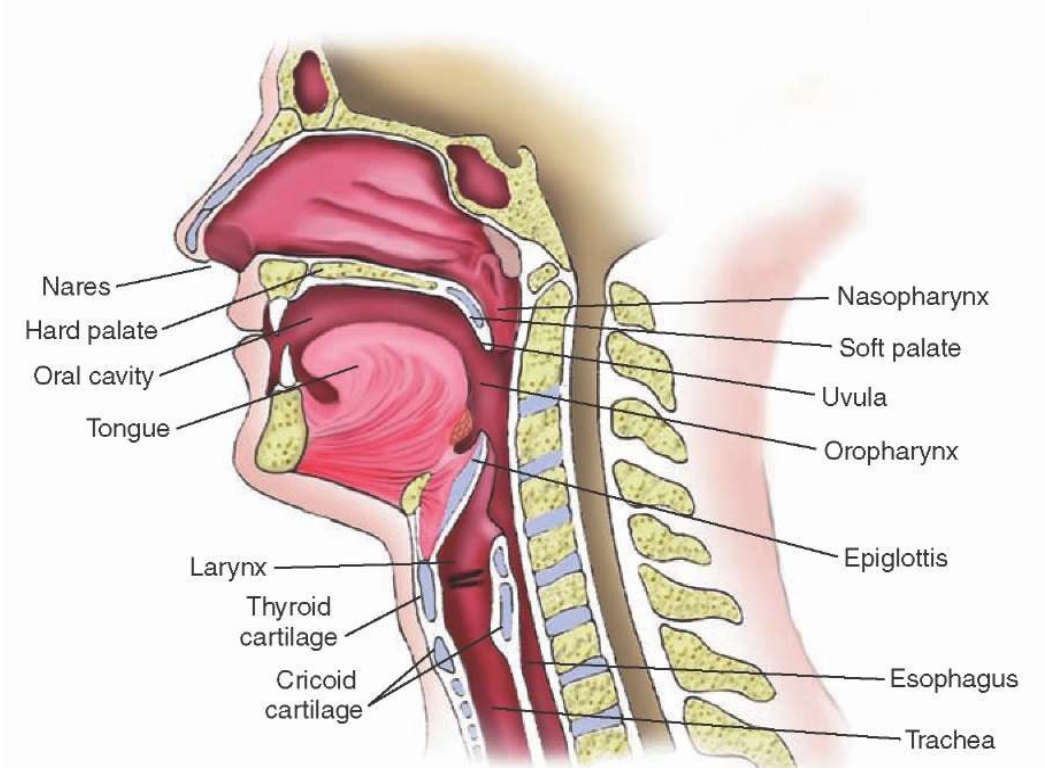

Figure 1. Anatomy of upper airway.

SUPRAGLOTTIC AIRWAY DEVICES:

Supraglottic devices have been widely used as an alternative to tracheal intubation during general anaesthesia. Supraglottic airway devices have become a standard fixture in airway management, filling a niche between the face mask and tracheal tube in terms of both anatomical position and degree of invasiveness. They are easily inserted, better tolerated with lesser hemodynamic changes, have favourable respiratory mechanics and decreased airway morbidity. These devices sit outside the trachea but provide a hands-free means of achieving a gas-tight airway.

I-GEL:

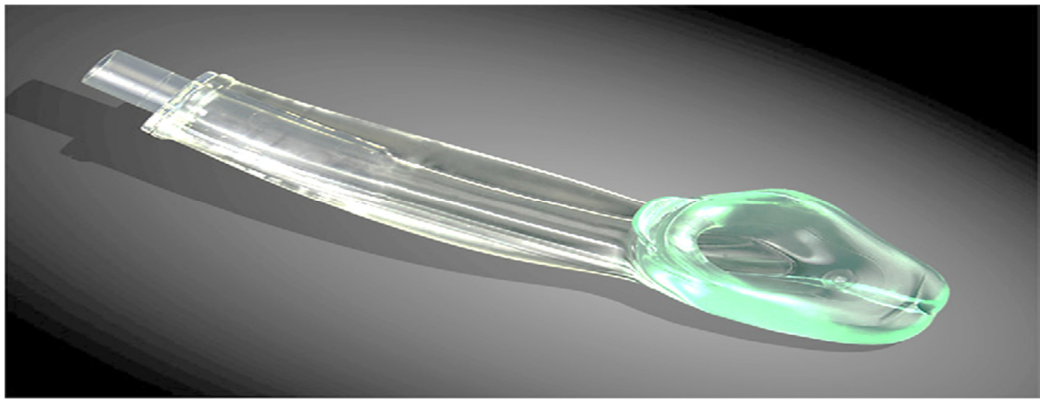

Figure 2.I gel - full view.

DESCRIPTION OF I-GEL

I-gel (Intersurgical Ltd.., Wokingham, Berkshire, UK) is a single use, supraglottic airway management device. I-gel is made up of medical grade thermoplastic elastomer, which is soft, gel like, transparent and designed to anatomically fit the pharyngeal, laryngeal and perilaryngeal structures without an inflatable cuff because of its non-inflatable seal; I-gel has minimal risk of tissue

compression. Design of I-gel makes it an anatomical device as the distal soft non-inflatable cuff achieves a mirrored impression of the pharyngeal, laryngeal and perilaryngeal structures and thus positions itself over laryngeal framework providing a reliable perilaryngeal seal. The tip of the distal non inflatable cuff lies in the proximal opening of esophagus, isolating the esophageal opening from the laryngeal inlet. Since the distal tip of the device fits snugly and anatomically correctly into the upper esophageal opening, the distal opening of the gastric channel allows for the passing of a nasogastric tube to empty the stomach contents and can facilitate the venting of gas from the stomach.

The proximal end of the cuff has an epiglottic rest with a ridge. The rest prevents the epiglottis from down folding whereas the ridge is in contact with the base of the tongue preventing the upward and outward movement of the I-gel. It consists of elliptical buccal cavity stabilizer which incorporates a circular airway lumen and a lumen for gastric tube insertion. The gastric channel runs through the device from its proximal opening at the side of the flat connector wing to the distal tip of the non-inflatable cuff. Size1 I-gel does not have a gastric lumen. The elliptical shape provides vertical stability and axial strength after insertion. It also has a built-in bite block incorporated within the tube. There is a horizontal line in the integrated bite block (in size3, 4 and 5) which is a guide for correct depth of insertion. If correctly inserted it should coincide with the patient's teeth. The paediatric sizes don't have the horizontal line due to greater variability in the length of the Oro-pharyngeal-laryngeal arch in children. It is latex free supraglottic device. Device selection is usually done on patient weight basis.

Table 1. I gel - different sizes and recommended corresponding patient weight (in kilograms).

I-GEL SIZE	PATIENT SIZE	PATIENT WEIGHT (Kg)	I-GEL COLOUR
1	NEONATE	2-5	PINK
1.5	INFANT	5-12	BLUE
2	SMALL PEDIATRIC	10-25	GREY
2.5	LARGE PEDIATRIC	25-35	WHITE
3	SMALL ADULT	30-60	YELLOW
4	MEDIUM ADULT	50-90	GREEN
5	LARGE ADULT	> 90	ORANGE

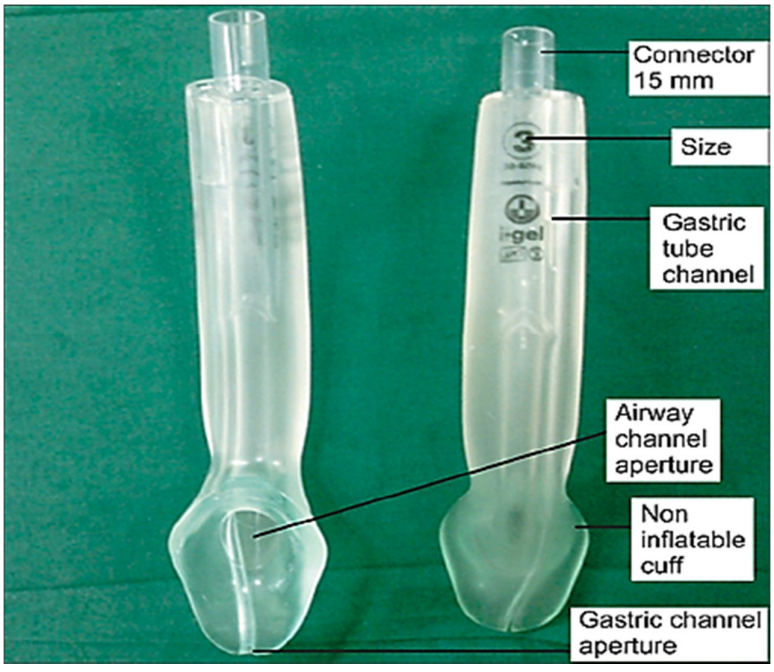

Figure 3. Parts of I - gel.

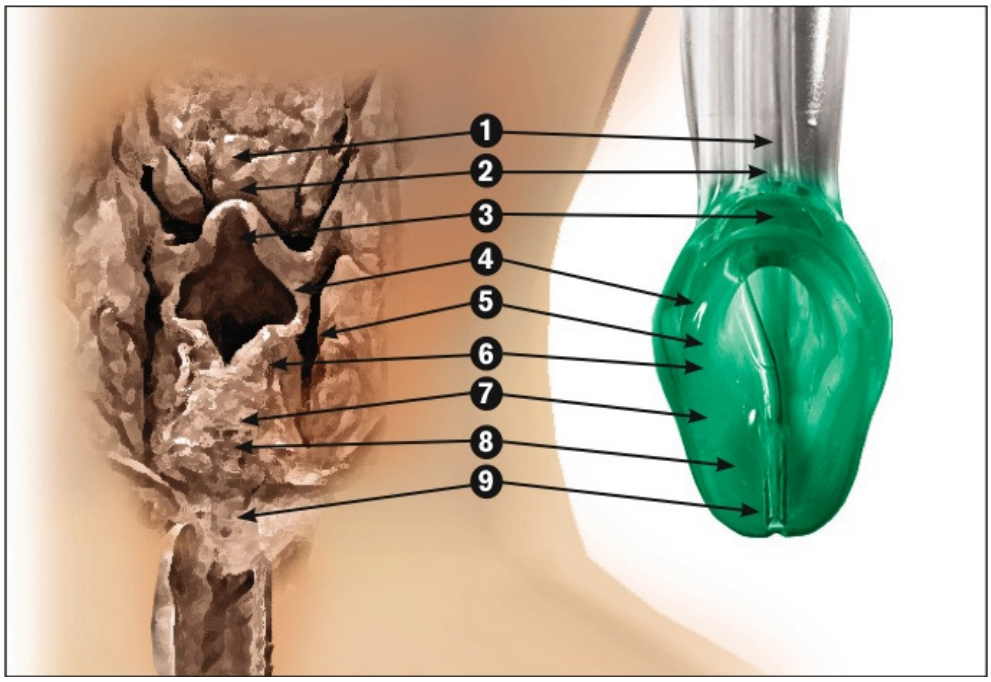

Figure 4. View of the I-gel cuff in relation to the laryngeal framework. 1.Tongue, 2.Base of tongue, 3.Epiglottis, 4.Aryepiglottic folds, 5.Pyriform fossa, 6.Posterior cartilages, 7.Thyroid cartilage ,8.Cricoid cartilage, and 9.Upper esophageal opening.

The firmness of the tube section and its natural Oro-pharyngeal curvature allows the device to be inserted by grasping the proximal end of I-gel and helps to glide the leading edge against the hard palate into the pharynx. It is not necessary to insert the fingers into the mouth of the patient for full insertion. The innovative 15mm connector serves a number of functions- To provide a standard 15mm connection to the anaesthetic system or patient connection, provide an integral bite block, reduces the possibility of the airway channel, as a guide to correct positioning – the integral part of the bite-block is marked with a horizontally placed black line, which signifies the optimum position of the teeth while the device is in situ (not applicable to the paediatric sizes).

PRE-USE CHECKS:

- Inspecting the device carefully, checking the airway patency and confirmation that there are no foreign bodies or a bolus of lubricant obstructing the distal opening of the airway or gastric channel.

- Careful inspection of the device, ensuring surfaces are smooth and intact and also that the gastric channel is patent.

- Discarding the device if the airway tube or the body of the device looks abnormal or deformed.

- Checking if the 15mm connector fits the patient connection.

INSERTION TECHNIQUE:

An appropriate size of I-gel has to be chosen and prepared prior to insertion. The I-gel is supplied in a protective cradle or cage pack to ensure the device is retained in the correct flexion prior to use and also acts as a base for lubrication. The I-gel must always be separated from the cradle or cage pack prior to insertion. A smaller and larger size of the I-gel should be readily available. Adequate preparation, proper lubrication of the device and correct positioning of the head and neck with optimum mouth opening is the key to a successful insertion of I-gel. Pre-oxygenation is ensured before insertion of device.

STEPS FOR INSERTION:

1. I-gel should be lubricated on the posterior aspect of distal non inflatable cuff and firmly grasped along the integral bite block. The device is positioned so that the I-gel cuff outlet is facing towards the chin of the patient.
2. The patient should be placed in the 'sniffing the morning air' position with head extended and neck flexed. The chin should be gently pressed down before proceeding to insert the I-gel.
3. The leading soft tip is introduced into the mouth of the patient in a direction towards the hard palate.
4. I-gel is glided downwards and backwards along the hard palate with a continuous but gentle push until a definitive resistance is felt.
5. It is not necessary to insert fingers or thumbs into the patient's mouth during the process of inserting the device. If there is early resistance during insertion, a 'jaw thrust', 'Insertion with deep rotation' or triple manoeuvre is done.
6. If this does not solve the problem, a smaller size of I-gel is tried.
7. At this point the tip of the airway should be located into the upper esophageal opening and the cuff should be located against the laryngeal framework. The incisors should be resting on the integral bite-block.
8. I-gel should be taped down from 'maxilla to maxilla'. If required, an appropriate size nasogastric tube may be passed down the gastric channel.
9. The device is then connected to the breathing apparatus.

REMOVAL OF THE DEVICE:

1. The device is removed once consciousness is regained and the protective reflexes are present, after suction of the oral cavity and pharynx.

2. I-gel can be removed when the patient is awake and easily arousable with verbal commands.

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PROSEAL LARYNGEAL MASK AIRWAY

DESCRIPTION OF PROSEAL LMA:

The proseal LMA (P-LMA) was introduced by Dr.Archie Brain in 2000 (Intavent Orthofix, Maidenhead, UK).

It has four main parts: the cuff, inflation line with pilot balloon, airway tube, and drain (gastric access) tube. All components are made from silicone and are latex-free. It is available in six sizes

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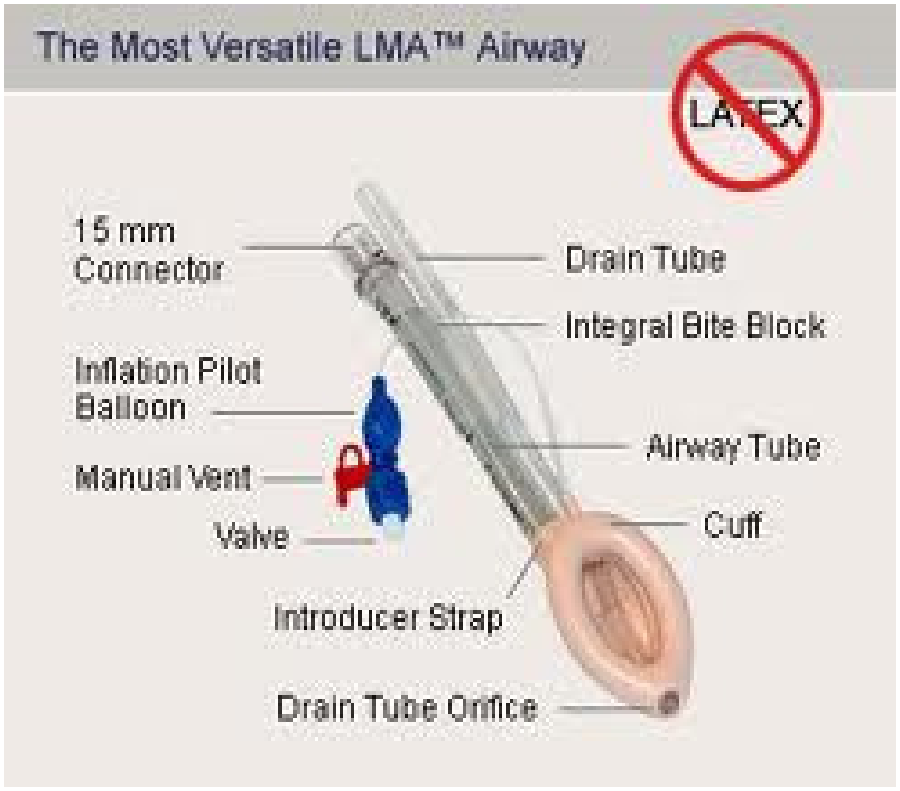

Figure 5. Proseal- LMA - full view.

Table 2. Characteristics of P-LMA of different sizes.

Size	Patient weight	Max. Cuff inflation(ml)	Max. Gastric tube size(Fr)	Max. Fiberscope size(mm)	Drain tube length(cm)	ETT uncuffed (ID in mm)
1.5	5-10	7	10	-	18.2	4.0
2	10-20	10	10	-	19.0	4.0
2.5	20-30	14	14	-	23.0	4.5
3	30-50	20	16	-	26.5	5.0
4	50-70	30	16	4	27.5	5.0
5	70-100	40	18	5	28.5	6.0_{cuffed}

The airway tube of the proseal LMA is shorter and smaller in diameter than that of the LMA-Classic and is wire reinforced, which makes it more flexible. There is a locating strap on the anterior distal tube to prevent the finger slipping off the tube and to provide an insertion slot for the introducer tool. An accessory vent under the drainage tube in the bowl prevents secretions from pooling and acts as an accessory ventilation port. The proseal LMA has a deeper bowl than the LMA-Classic and does not have aperture bars. There is a bite block between the tubing at the level where the teeth would contact the device.

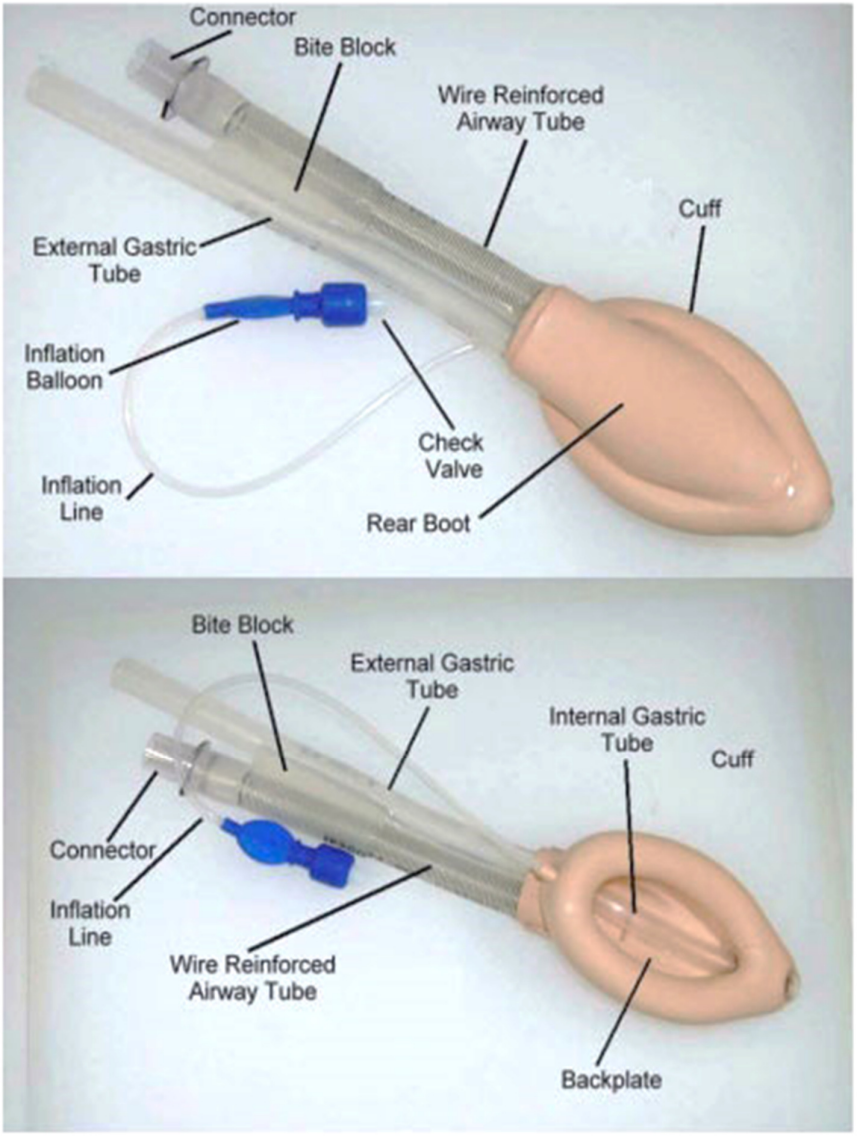

Figure 6. Parts of proseal LMA.

The drain tube is parallel and lateral to the airway tube until it enters the cuff bowl, where it continues to an opening in the tip that is sloped anteriorly. When the proseal LMA is correctly positioned, the cuff tip lies behind the cricoid cartilage at the origin of the esophagus. It allows liquids and gases to escape from the stomach, reduces the risks of gastric insufflation and pulmonary aspiration, allows devices to pass into the esophagus, and provides information about the proseal LMA position. The drain tube is designed to prevent the epiglottis from occluding the airway tube, eliminating the need for airway bars. A gastric tube can be passed into the esophagus through the drainage port. A plastic supporting ring around the distal drain tube prevents the tube from collapsing when the cuff is inflated.

The proseal LMA has a second dorsal cuff. This pushes the mask anteriorly to provide a better seal around the glottic aperture and helps to anchor the device in place. The dorsal cuff is not present on sizes 1.5, 2 and 2.5. The ventral cuff is larger proximally to improve the seal.

A silicone-coated malleable metal introducer to facilitate placement of the proseal LMA is available. It has a curved, malleable silicone-coated blade with a guiding handle. The distal end fits into the locating strap, and the proximal end fits into the airway tube.

INSERTION TECHNIQUES:

1) FINGER INSERTION TECHNIQUE:

The patient is positioned as for regular laryngoscopy, with neck flexion and head extension. The cuff is deflated fully and posterior part is lubricated with water based gel. The device is held like a pen, index finger is at the point where the mask joins the tube. After opening the mouth, insertion is done along the midline with the help of the longitudinal black line on the LMA, with the device pressing on the hard palate. The index finger moves in a cranioposterior direction. Resistance is felt on reaching the upper esophageal sphincter. The non dominant

hand helps in widening the cranio-pharyngeal angle to aid insertion and during removal of the index finger from the mouth. The mask is inflated via the pilot balloon to a pressure not more than 60 cmH_2O. A bite block is inserted and should remain in place until the LMA is removed, in order to reduce the possibility of biting and obstruction of the airway or damage to the tube.

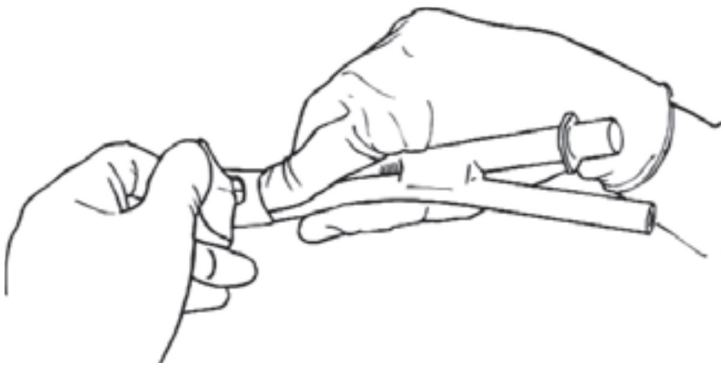

Figure 7. P-LMA held with index finger in the strap.

Figure 8. P-LMA - Wrist flexed with index finger in the strap.

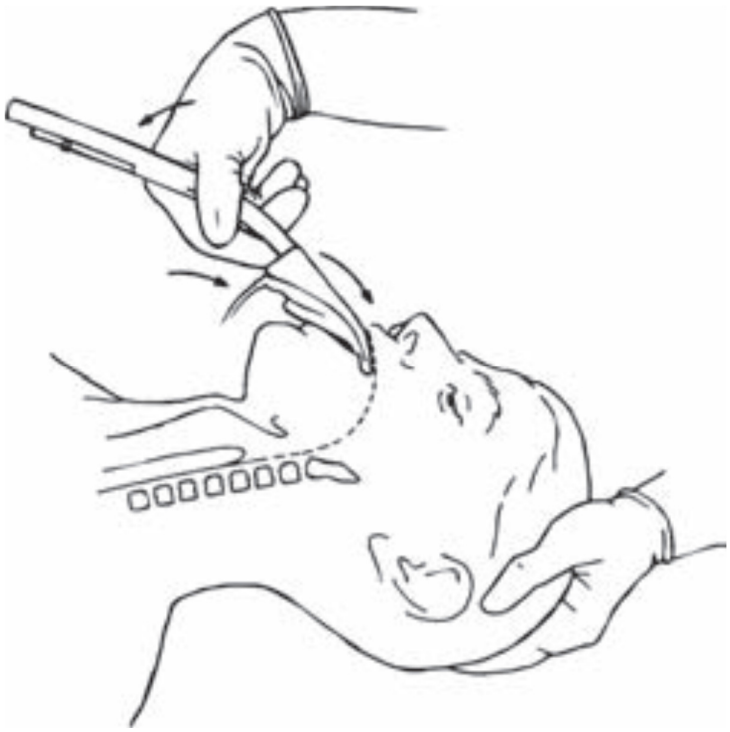

Figure 9. P-LMA - Mask slid inward, sliding the index finger.

Figure 10. P-LMA- Advancing into hypopharynx till resistance is felt.

2) INTRODUCER METHOD:

Instead of the index finger, a metal introducer is used. The metal introducer is fit onto the device at the retaining strap found at the end of the cuff. The airway and drain tubes are folded over the convex part of the introducer. Along the curvature of the introducer, in one smooth sweeping motion the P-LMA is inserted till resistance of upper oesophageal sphincter is felt.

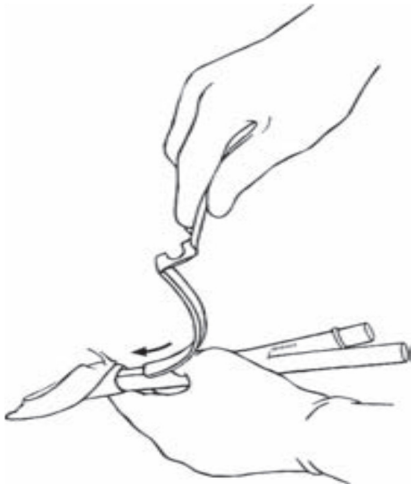

Figure 11.P-LMA - Tip of Introducer placed into strap.

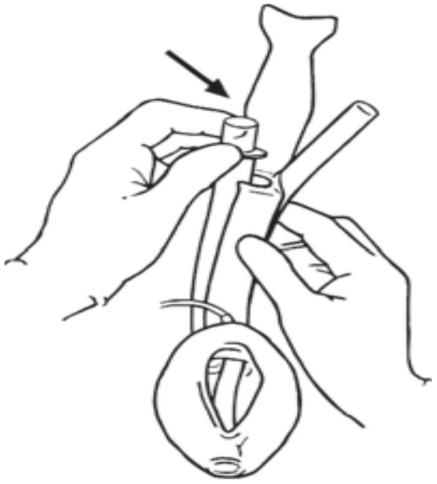

Figure 12. P-LMA -Tubes are folded around introducer.

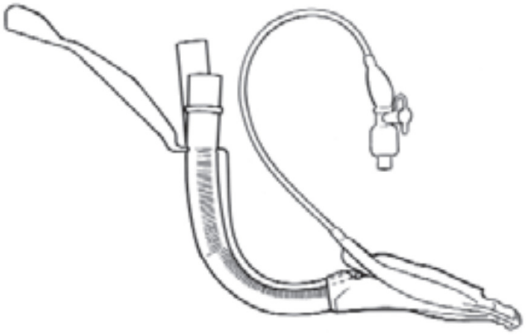

Figure 13. LMA proseal mounted on introducer.

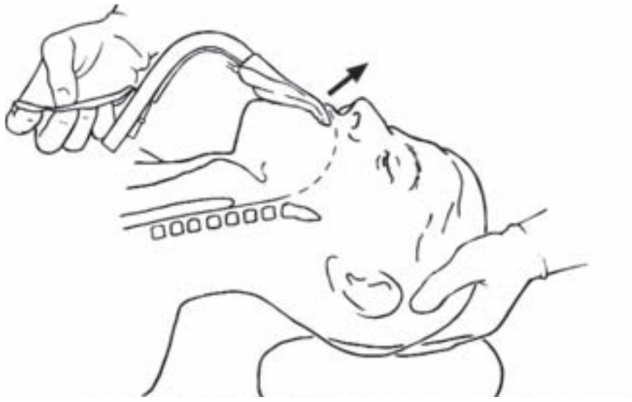

Figure 14. P-LMA - Tip of cuff pressed against hard palate.

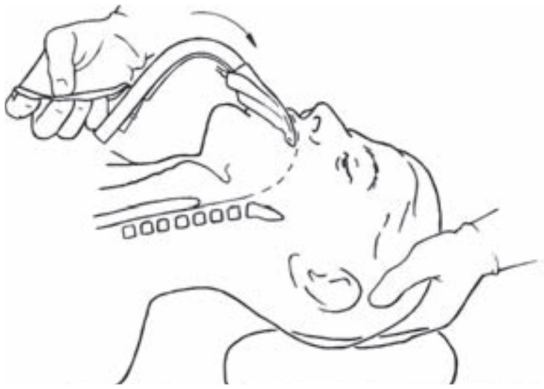

Figure 15. Pressing the cuff of P-LMA against hard palate.

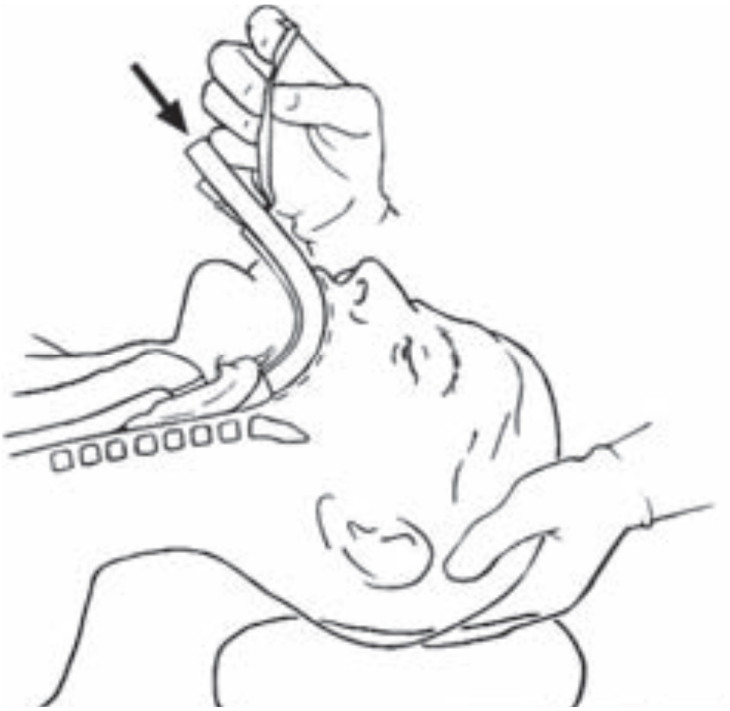

Figure 16. Advancing P-LMA into hypopharynx until resistance is felt.

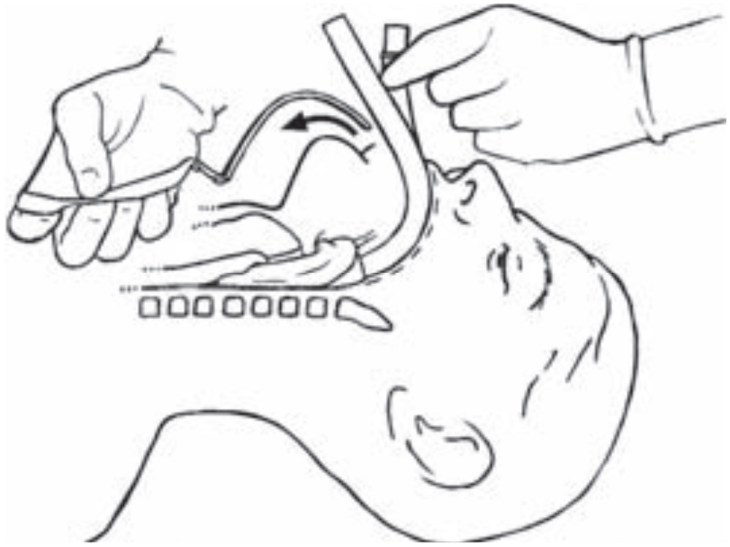

Figure 17. Holding the tubes of P-LMA while removing introducer.

3) GUM ELASTIC BOUGIE GUIDED METHOD:

The bougie is inserted blindly or with laryngoscopy, into the esophagus. Then the drain tube is railroaded over the bougie.

CUFF INFLATION:

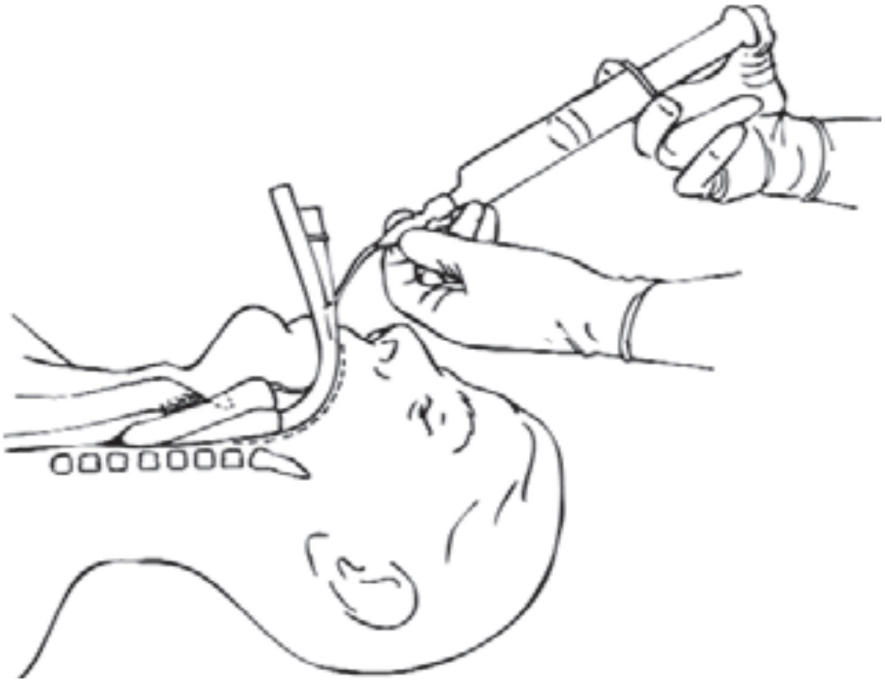

Figure 18. Cuff inflation of P-LMA.

After the proseal LMA has been inserted, the cuff should be inflated with enough air to achieve an intracuff pressure of up to 60 cm H2O. During insertion and cuff inflation, the front of the neck should be observed to see if the cricoid cartilage moves forward, indicating that the mask has correctly passed behind it.

CONFIRMATION AFTER PLACEMENT:

1. A small amount (1 to 2 ml) of water-based gel or soap bubble is placed on the end of the drainage tube that protrudes from the mouth and positive pressure applied to the airway tube. If the proseal LMA is properly placed, there should be a slight up/down movement of the lubricant. The soap bubble may move when the lubricant gel does not. If there is no movement or the bolus is ejected, the mask may not be correctly placed.

2. The drainage tube should be tested for patency. This can be done by passing a gastric tube, a flexible endoscope, or a lighted stylet through the drainage tube. Easy passage indicates correct positioning; difficulty suggests that the mask should be repositioned, even if ventilation is satisfactory.

3. The suprasternal notch tap test involves tapping the suprasternal notch or cricoid cartilage and observing simultaneous movement of the soap bubble at the proximal end of the drainage tube. However, this can produce both false positive and false negative results.

4. Proper proseal LMA positioning can also be detected by inserting a lighted stylet. If the tip is folded over, the stylet will meet resistance 1 to 2 cm from the tip of the drain tube.

INSERTION PROBLEMS:

The complications include;

- Laryngospasm, bronchospasm,
- Trauma to the airway,
- Regurgitation and aspiration,
- Malfunction of cuff, and
- Malposition may be due to folding over of tip, tip of drain tube over the glottis opening or insufficient depth of insertion.

MATERIALS AND METHODS

STUDY CENTRE: This study "COMPARISON OF CLINICAL PERFORMANCE OF TWO SUPRAGLOTTIC AIRWAY DEVICES, I-GEL WITH PROSEAL - LARYNGEAL MASK AIRWAY (LMA) IN PATIENTS UNDERGOING ELECTIVE SURGERIES – A PROSPECTIVE RANDOMIZED STUDY " was conducted in Department of Anaesthesiology, Thanjavur medical college, Thanjavur.

STUDY POPULATION: After approval from the Ethical Committee, informed consent was obtained from seventy patients (American Society of Anesthesiologists physical status-ASA grade I and II) scheduled for puerperal/laparoscopic sterilisation under general anaesthesia, after explaining about the supraglottic airway devices.

STUDY DESIGN: This was a Prospective, Randomized, Single Blinded (to the patient) study.

SAMPLE SIZE CALCULATION:

Based on the following formula,

$$n = \frac{2\,(Z_\alpha + Z_\beta)^2\,\sigma^2}{\Delta^2}$$

Where,

Z_α was the standard normal value (95% confidence interval) = 1.96.

$Z_{\beta\ was}$ the power of the test (80%) = 0.84.

Mean insertion time for I gel = 11.12 secs.

Mean insertion time for proseal LMA = 15.13 secs.[22]

σ was the standard deviation = 2.42.

Δ = mean difference/effect size.

= 4.01 / 2.42

= 1.65

By applying these values, the sample size was 70 (35 in each group).

PERIOD OF STUDY: August 2015 to October 2017.

INCLUSION CRITERIA:

1. Adult patients of aged between 20 and 35yrs,
2. ASA grade I and II,
3. Patients undergoing puerperal/laparoscopic sterilization.
4. Mallampatti grade 1 and 2

EXCLUSION CRITERIA:

1. Patients with mouth opening less than 2.5 cms,
2. Patients with risk of aspiration such as full stomach, hiatus hernia, gastro esophageal reflux disease,
3. Upper respiratory tract infection/sore throat,

4. Patients with abnormal or distorted anatomy of pharynx

5. ASA grade III and IV,

6. BMI>30,

7. Mallampatti grade 3 and 4,

8. Cervical spine disease,

METHODOLOGY:

The 70 patients were assigned to the device (I-gel and P-LMA) randomly by using a block of 10 random permutations of numbers 0 to 9. For block of 10 patients, I-gel was assigned for digits 0-4 and P-LMA for digits 5-9. Totally 7 blocks of 10 random permutations of numbers were used to allot randomly 35 patients for each group.

Patients under this study were randomized to one of the two groups, with 35 patients in each group.

Group A: I-GEL (N = 35)

Group B: PROSEAL LARYNGEAL MASK AIRWAY (N = 35).

Pre-anaesthetic evaluation was done on the day before surgery. It included general condition of the patient, airway assessment, nutritional status and body weight of the patient and detailed examination and assessment of cardiovascular and respiratory system.

All patients were pre-medicated with Tablet Alprazolam 0.5mg and Tablet Ranitidine 150 mg on the night before the day of surgery. All patients were kept nil per oral 6 hours for solids and 2 hours for clear fluids prior to surgery.

On arrival to operation theatre, an 18 Gauge intravenous cannula was placed into the largest vein on the dorsum of hand and attached to a normal saline infusion.

All the drugs were maintained at adequate temperature and used within 15 minutes of preparation. The patient's head was placed on a pillow of 10 cms with neck flexed and head extended. The patient was connected to a monitor , which recorded heart rate, non invasive blood pressure including systolic, diastolic and mean arterial pressures, continuous ECG monitoring and oxygen saturation. The baseline values of all these parameters were recorded.

The standard pre-use test was performed. I-gel or proseal LMA was lubricated with water soluble jelly on the posterior surface and kept ready. I-gel was used in Group-A patients. Size of I-gel was decided according to body weight of the patient (I-Gel size 3: body weight between 30 and 60 kgs, size 4: weight between 50 and 90kgs). Proseal LMA was used in Group-B patients. Size of proseal LMA was decided according to body weight of the patient (proseal LMA size 3: weight between 30 and 50 kgs, size 4: weight between 50 and 70kgs).

All patients were pre-oxygenated with 100% Oxygen for 3 minutes with facemask. Anaesthesia was induced with injection Propofol 2-2.5mg/kg and Fentanyl 1.5 µg/kg. After checking for ventilation,neuromuscular blockade was achieved with Injection. Atracurium 0.5mg/kg. Anaesthetic depth was deepened with 1% Sevoflurane in oxygen using bag and mask ventilation for 3 minutes after which patient was kept in 'sniffing the morning air' position and the allotted device of appropriate size, according to weight of the patient was inserted in midline against the hard palate and push down into hypopharynx till resistance was met. The cuff was inflated (if proseal-LMA was used) with recommended volume of air (20ml, 30ml of air for sizes 3, 4 respectively). The device was connected to breathing circuit(circle system) and patient was ventilated. Maintenance was achieved by Nitrous oxide and Oxygen in 2:1 ratio with 1% Sevoflurane and intermittent doses of intravenous - Atracurium 0.1mg/kg.

Insertion time was recorded by an independent observer and defined as time interval between picking up the device and securing an effective airway.

An effective airway was judged by bilateral symmetrical chest movements, a square wave capnography trace, lack of gastric insufflation and absence of leak. If an effective airway was not achieved, the device was removed and three attempts were taken before recording failure of insertion. If three attempts were unsuccessful either an alternative device would had been inserted or trachea would had been intubated.

The number of insertion attempts was recorded. The cuff of proseal LMA was inflated with air and maintained at a pressure of less than 60 cms of water with the help of hand held aneroid manometer. The tube was fixed by taping over chin.

The airway sealing pressure was determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 litres per minute and recording the airway pressure at which equilibrium was achieved. At this time, gas leakage was determined at the mouth by the audible leak or by detection of an audible noise using a stethoscope placed just lateral to thyroid cartilage.

A lubricated gastric tube of appropriate size was placed into the stomach through the gastric channel. The ease of placement of gastric tube was recorded and its correct placement was confirmed by injection of air and epigastric auscultation or aspiration of gastric contents. Failure of gastric tube placement was also recorded and defined as failure to advance the gastric tube into the stomach within two attempts.

Intra-operative heart rate (HR) in beats per minute, non-invasive blood pressure (NIBP) in mm of Hg and oxygen saturation (SpO2) in percentage was recorded at 1 minute ,5 minutes, 10 minutes and 15 minutes after insertion of device.

At the end of surgical procedure anaesthesia was discontinued, patient was reversed with standard doses of injection neostigmine 0.05mg/kg with glycopyrollate 0.01mg/kg intravenously and once the patient was awake, responsive and met all the

reliable signs of recovery from neuromuscular blockade, the device was removed. Post extubation cough, laryngospasm, blood staining of the device and tongue, lip and dental trauma were recorded. Regurgitation of gastric contents was also assessed. Post operative sore throat was assessed in post-anaesthesia care unit.

STATISTICAL METHODS:

For continuous variables following normal distribution, it was expressed as mean ± standard deviation otherwise median (Inter-quartile range). Categorical variables were expressed as either percentages or proportions. Comparison of continuous variables was done by independent sample‘t’test. Comparison of categorical variables was done by Chi square test or Fisher's exact test based on the number of observations.

All the data was entered in MS-Excel spread sheet. Analysis was carried out by SPSS V16.0. All the p values < 0.05 was considered as statistically significant.

OBSERVATION AND RESULTS

DEMOGRAPHIC VARIABLES:

AGE DISTRIBUTION:

Table 3. Mean age distribution (in years).

	Mean Age	N	SD
I-GEL	28.89	35	1.676
P-LMA	28.80	35	1.952
Total	28.84	70	1.807

p value = 0.844(not significant).

The mean age of patients in the groups I-gel and P-LMA were (28.89±1.676) and (28.80± 1.952) respectively. This data was statistically insignificant as the p value was >0.05. Thus, both the groups were comparable.

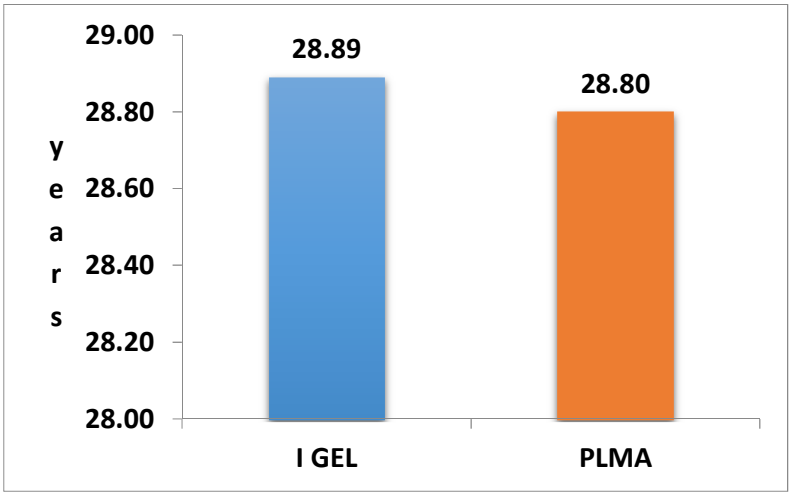

Chart 1. Mean age distribution (in years).

WEIGHT DISTRIBUTION :

Table 4. Mean weight distribution (in kgs).

		N	Mean	SD	p value
Weight	**I-GEL**	35	58.51	5.549	0.005
	P-LMA	35	53.51	8.480	

p value = 0.005 (significant)

The mean weight of patients in both the groups was statistically significant with a p value <0.05.

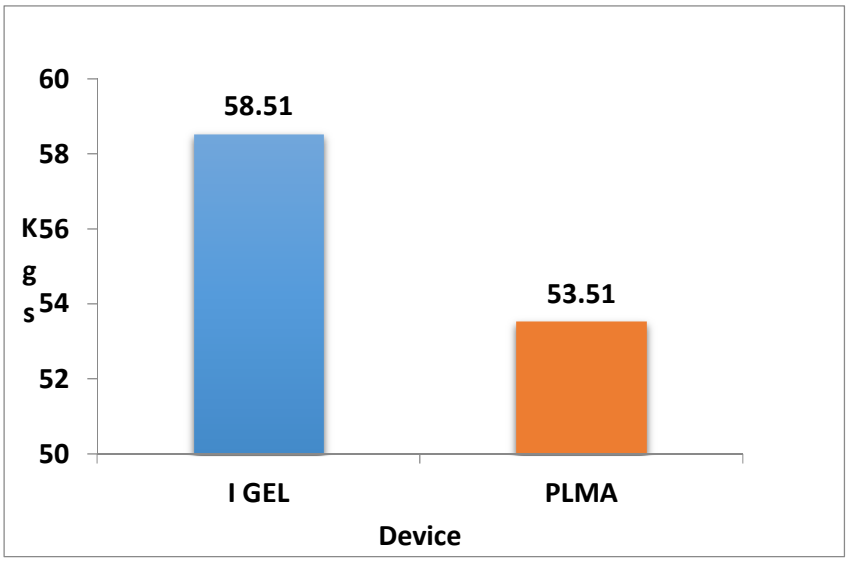

Chart 2. Mean weight distribution (in kgs)

ASA PHYSICAL STATUS DISTRIBUTION:

Table 5.ASA physical status distribution.

			ASA		
			1	**2**	**Total**
Device	**I-GEL**	**Count**	33	2	35
		% within Device	94.3%	5.7%	100.0%
	P-LMA	**Count**	32	3	35
		% within Device	91.4%	8.6%	100.0%

p value = 1.000 (not significant).

The ASA physical status distribution in both the groups were comparable as the p value was >0.05, which is not significant.

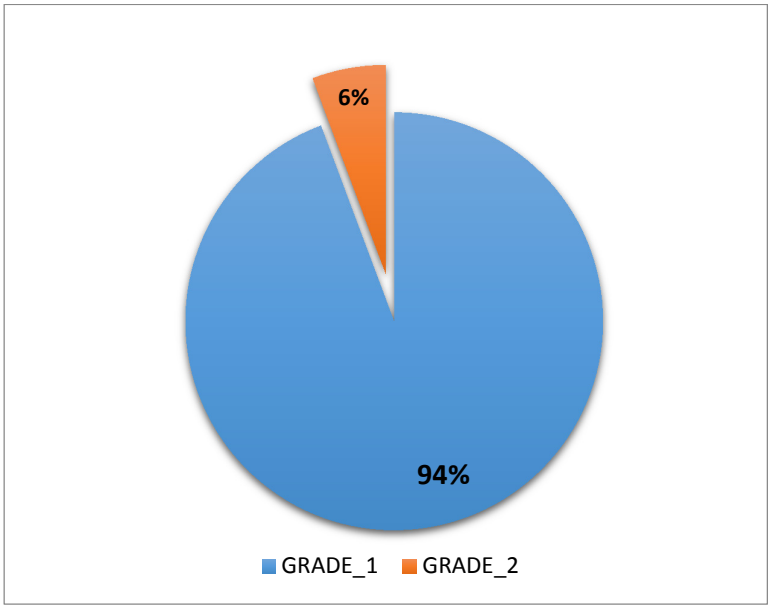

Chart 3. ASA grade in I-gel

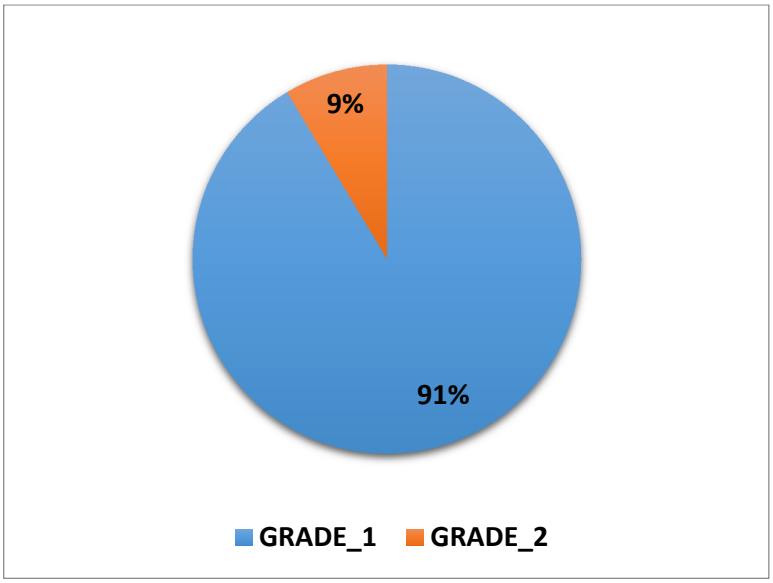

Chart 4. ASA grade in P-LMA

INSERTION TIME (in seconds):

Table 6. Mean insertion time for the device (in seconds).

		N	Mean	SD
Insertion time	**I-GEL**	35	12.40	1.063
	P-LMA	35	14.23	1.352

p value=0.000(significant)

The mean insertion time of I-gel and P-LMA were (12.40± 1.063) and (14.23± 1.352) respectively. This data was statistically significant as the p value was <0.05.

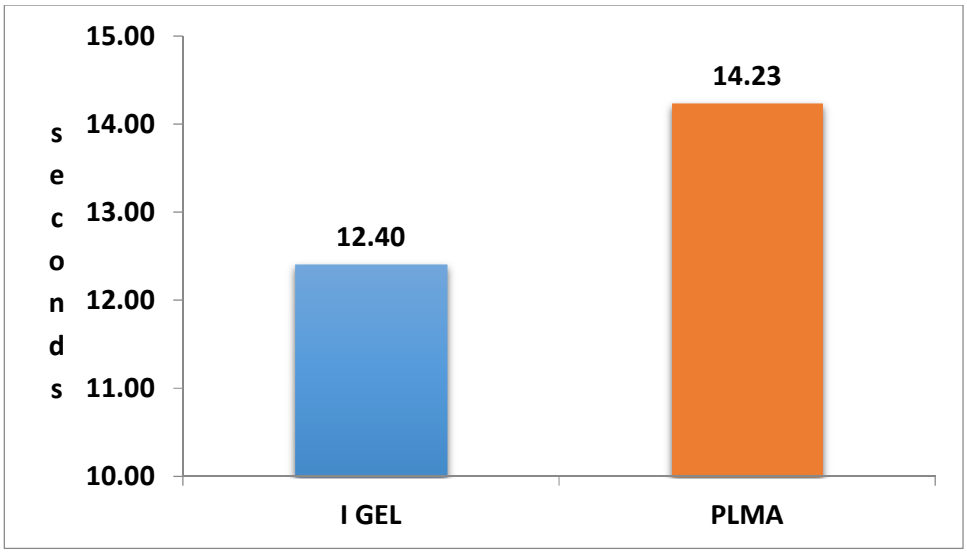

Chart 5. Mean insertion time (in seconds)

NUMBER OF ATTEMPTS TAKEN TO INSERT THE DEVICE:

Table 7. Number of attempts taken to insert the device.

			Number of attempts		Total
			1	**2**	
Device	**I-GEL**	**Count**	34	1	35
		% within Device	97.1%	2.9%	100.0%
	P-LMA	**Count**	31	4	35
		% within Device	88.6%	11.4%	100.0%

p value = 0.356 (not significant).

The number of attempts taken to insert the device in the groups I-gel and P-LMA were comparable, as the p value was > 0.05, which was not significant.

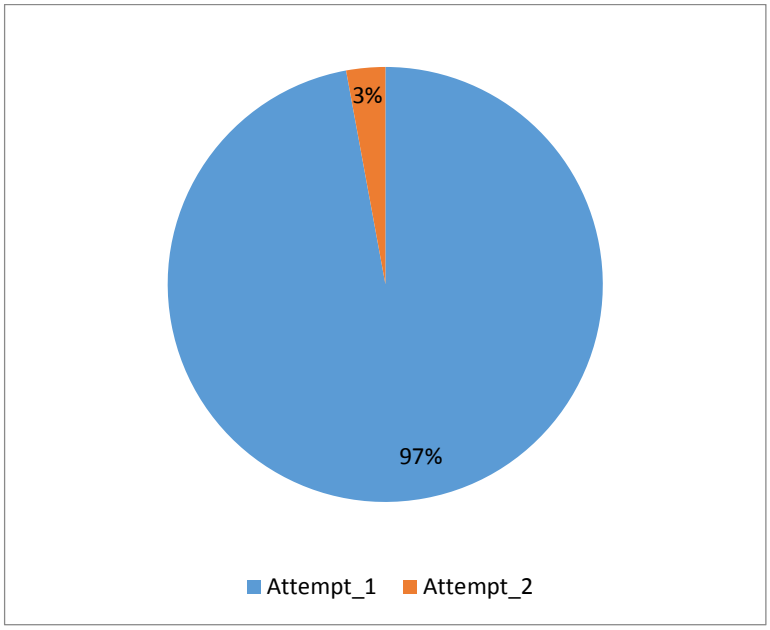

Chart6. Number of attempts taken to insert I-gel.

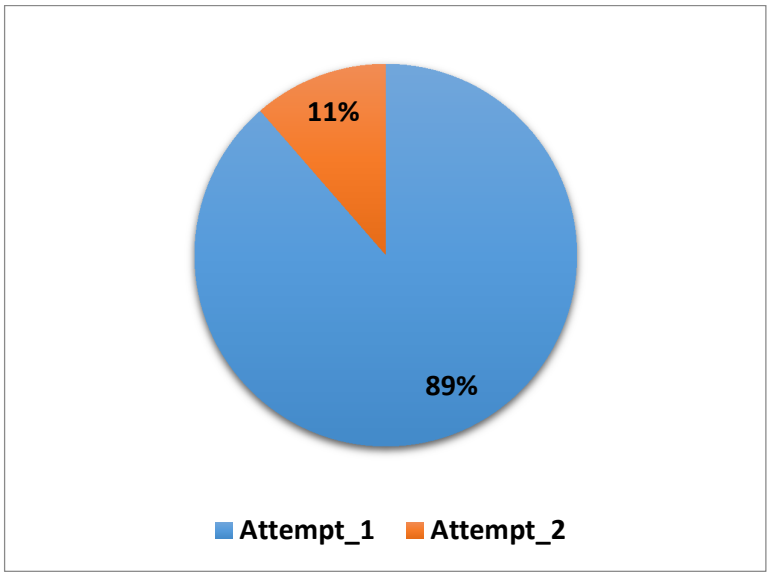

Chart7. Number of attempts taken to insert P-LMA.

AIRWAY SEALING PRESSURE DISTRIBUTION:

Table 8. Airway sealing pressure distribution (in cms of H2O).

	Mean	N	SD
I GEL	23.40	35	1.063
P-LMA	28.29	35	1.152
Total	25.84	70	2.695

p value = 0.000 (significant).

The mean age of patients in the groups I-gel and P-LMA were (23.40±1.063) and (28.29± 1.152) respectively. This data was statistically significant as the p value was <0.05.

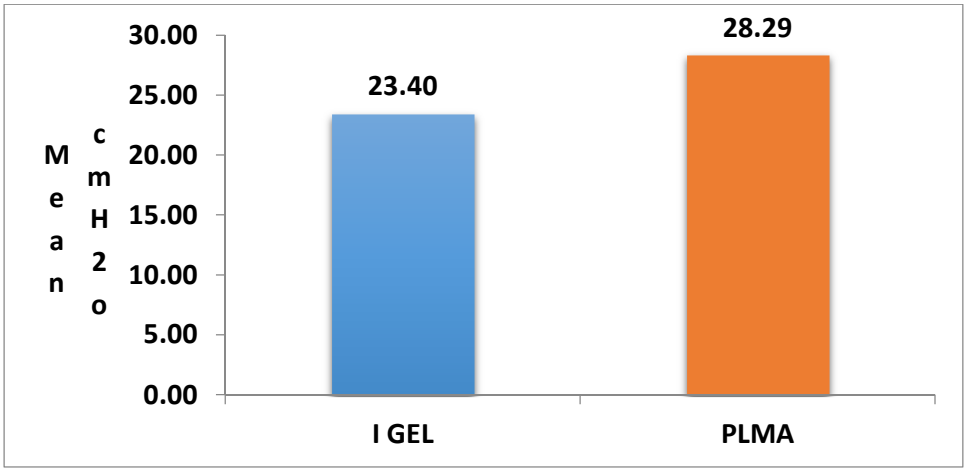

Chart8. Mean airway sealing pressure(incms H2O)

NUMBER OF ATTEMPTS TAKEN FOR GASTRIC TUBE INSERTION:

Table 9. Number of gastric tube attempts by both groups.

			Number of attempts		
			1	**2**	**Total**
Device	**I-GEL**	**Count**	34	1	35
		% within Device	97.1%	2.9%	100.0%
	P-LMA	**Count**	34	1	35
		% within Device	97.1%	2.9%	100.0%

p value = 1.00 (not significant)

The number of attempts taken to insert the device in the groups I-gel and P-LMA, was not significant as the p value was >0.05.

HEMODYNAMIC CHANGES:

HEART RATE:

Table 10. Intergroup comparison of mean heart rate (bpm) changes in response to insertion of the device.

	Device	**N**	**Mean**	**SD**	**p value**
HR_basal	I-GEL	35	77.57	5.265	0.009
	P-LMA	35	82.51	9.410	
HR_1min	I-GEL	35	82.06	6.444	0.004
	P-LMA	35	87.37	8.342	
HR_ 5min	I-GEL	35	81.71	6.551	0.002
	P-LMA	35	86.03	8.463	
HR_10min	I-GEL	35	79.09	6.736	0.006
	P-LMA	35	84.06	7.829	
HR_15min	I-GEL	35	77.40	6.869	0.000
	P-LMA	35	83.80	7.231	

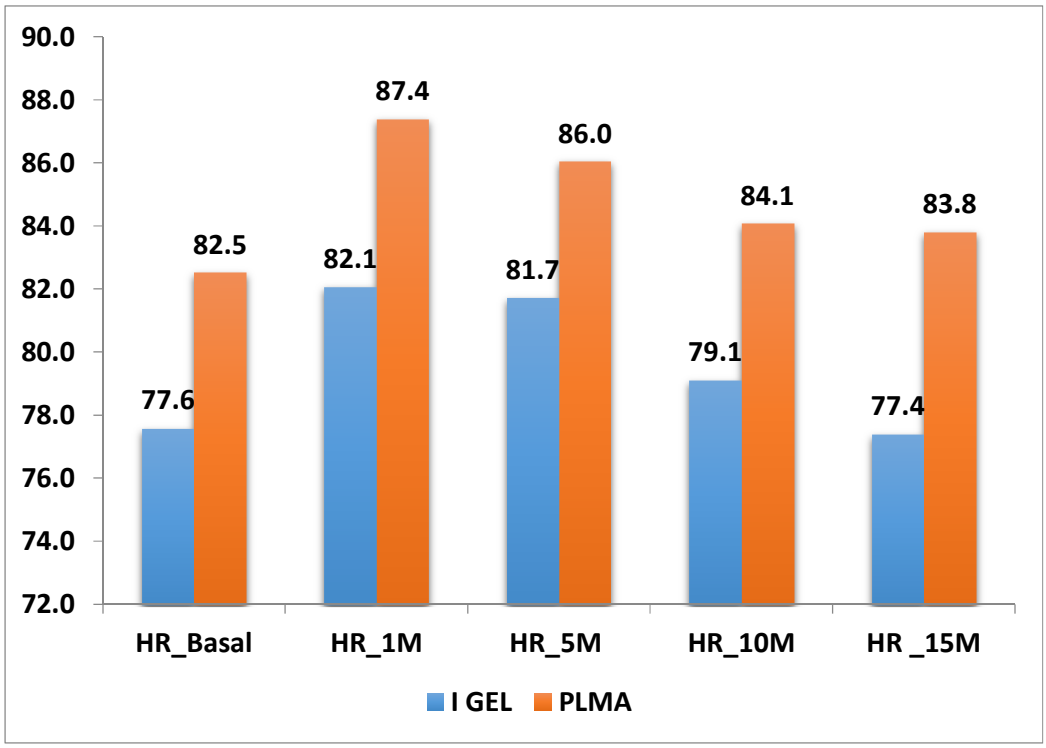

Chart9. Intergroup comparison of mean heart rate (bpm) changes in response to insertion of the device.

Comparing the mean heart rate in both the groups at corresponding timings showed that there was a significant difference at baseline(p value=0.009),1 minute(p value=0.004), 5 minutes(p value=0.002), 10 minutes(p value=0.006)and 15 minutes (p value=0.000) after insertion of the device. ($p < 0.05$ is significant).

SYSTOLIC BLOOD PRESSURE:

Table 11. Intergroup comparison of mean systolic blood pressure (mm Hg) changes in response to insertion of the device.

	Device	**N**	**Mean**	**SD**	**p value**
SBP_basal	I-GEL	35	124.34	7.300	0.218
	P-LMA	35	122.34	6.111	
SBP_1min	I-GEL	35	122.46	5.293	0.081
	P-LMA	35	119.60	7.908	
SBP_5min	I-GEL	35	118.09	6.767	0.173
	P-LMA	35	115.71	7.606	
SBP_10min	I-GEL	35	114,63	6.774	0.540
	P-LMA	35	113.60	7.204	
SBP_15min	I-GEL	35	114.29	5.629	0.314
	P-LMA	35	112.71	7.226	

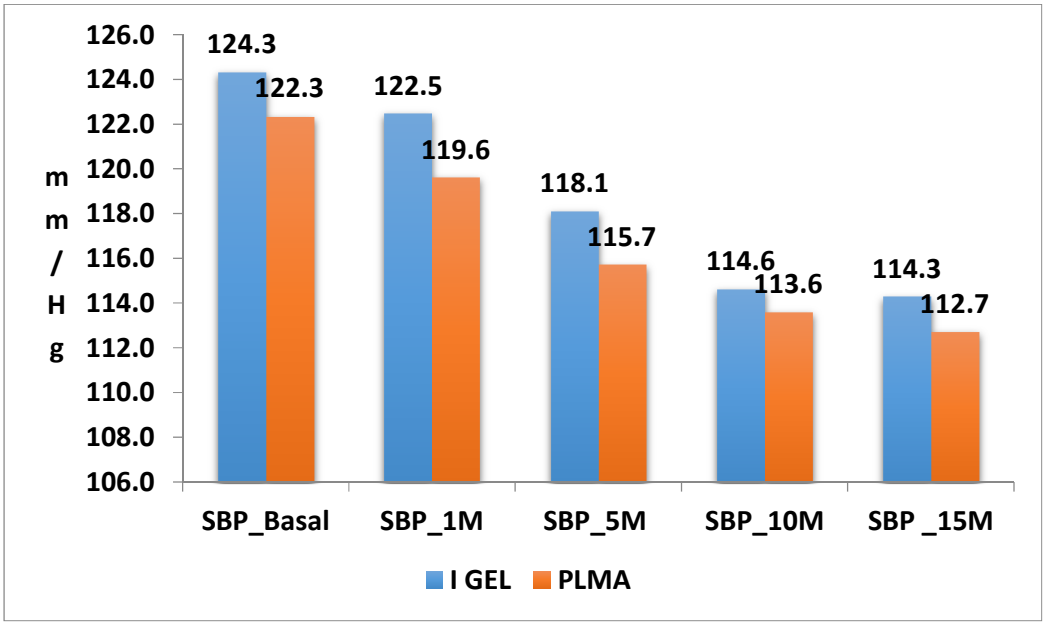

Chart 10. Intergroup comparison of mean systolicblood pressure (mm Hg) changes in response to insertion of the device.

Comparing the mean systolic blood pressure in both the groups at corresponding timings showed that there was no significant difference at baseline (p value=0.218),1 minute (p value=0.081), 5 minutes (p value=0.173), 10 minutes (p value=0.540) and 15 minutes (p value=0.314) after insertion of the device. ($p < 0.05$ is significant).

DIASTOLIC BLOOD PRESSURE:

Table 12. Intergroup comparison of mean diastolic blood pressure (mm Hg) changes in response to insertion of the device.

	Device	**N**	**Mean**	**SD**	**p value**
DBP_basal	I-GEL	35	74.83	7.622	0.052
	P-LMA	35	77.71	3.938	
DBP_1min	I-GEL	35	73.63	7.345	0.041
	P-LMA	35	76.69	4.562	
DBP_5min	I-GEL	35	71.89	6.850	0.009
	P-LMA	35	75.60	4.519	
DBP_10min	I-GEL	35	69.69	6.163	0.000
	P-LMA	35	74.83	4.308	
DBP_15min	I-GEL	35	69.51	5.607	0.000
	P-LMA	35	74.17	4.436	

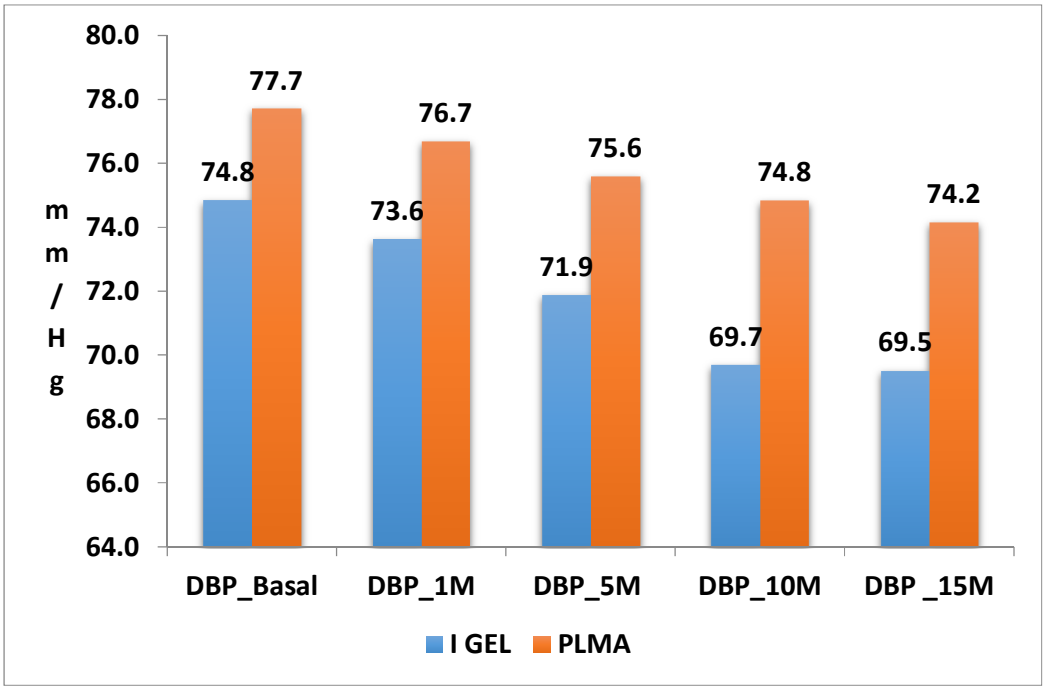

Chart11. Intergroup comparison of mean diastolic blood pressure (mm Hg) changes in response to insertion of the device.

Comparing the diastolic blood pressure in both the groups at corresponding timings showed that there was no significant difference at baseline as the p value = 0.052 (p >0.05 is non significant). There was a significant difference in diastolic blood pressure changes between the two groups at 1 minute (p value=0.041), 5 minutes (p value=0.009), 10 minutes (p value= 0.000), 15 minutes (p value=0.000) after insertion of the device (p <0.05 is significant).

MEAN ARTERIAL BLOOD PRESSURE:

Table 13. Intergroup comparison of mean arterial blood pressure (mm Hg) changes in response to insertion of the device.

	Device	**N**	**Mean**	**SD**	**p value**
MBP_basal	I-GEL	35	91.31	6.168	0.238
	P-LMA	35	92.77	3.797	
MBP_1min	I-GEL	35	89.91	5.260	0.376
	P-LMA	35	90.97	4.649	
MBP_5min	I-GEL	35	87.26	5.543	0.165
	P-LMA	35	88.86	3.851	
MBP_10min	I-GEL	35	84.71	5.108	0.008
	P-LMA	35	87.77	4.285	
MBP_15min	I-GEL	35	84.51	4.699	0.024
	P-LMA	35	87.06	4.485	

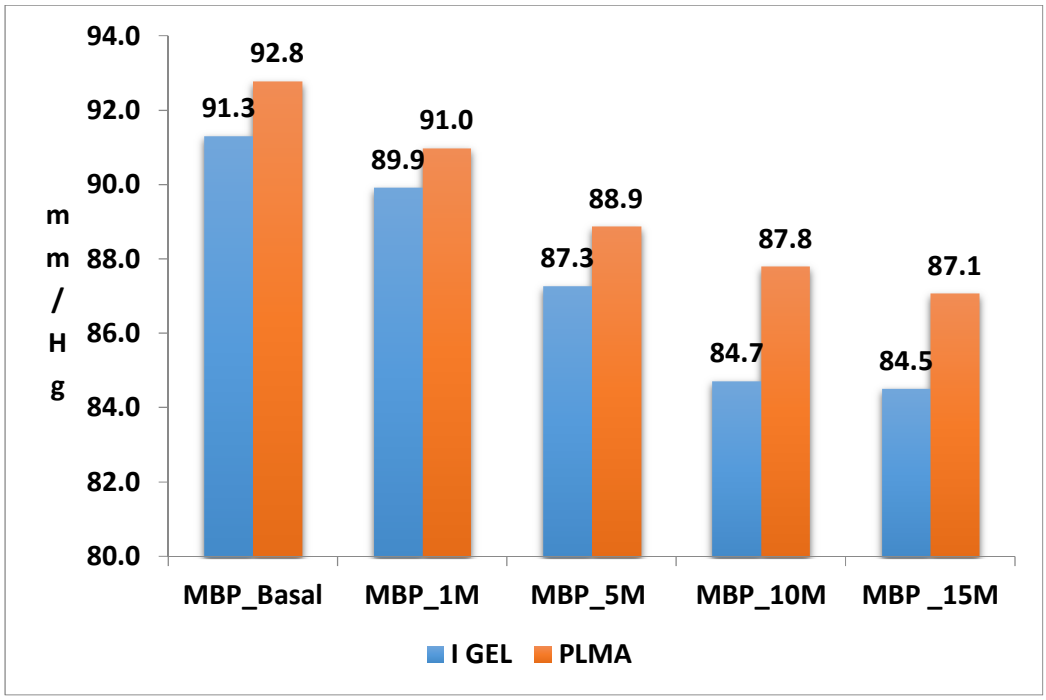

Chart 12. Intergroup comparison of mean arterial blood pressure (mm Hg) changes in response to insertion of the device.

Comparing the mean arterial blood pressure in both the groups at corresponding timings showed that there was no significant difference at baseline (p value = 0.238) , at 1 minute (p value=0.376) and 3 minutes (p value=0.165) after insertion of the device (p value >0.05 non significant). There was a significant difference in mean arterial blood pressure changes between the two groups at 10 minutes (p value=0.008) and at 15 minutes(p value=0.024) after insertion of the device (p<0.05 is significant).

OXYGEN SATURATION (SpO_2):

Table 14. Intergroup comparison of oxygen saturation(%) changes in response to insertion of the device.

	Device	**N**	**Mean**	**SD**	**p value**
SpO_2_basal	I-GEL	35	100.00	0.000	NA
	P-LMA	35	100.00	0.000	
SpO_2_1min	I-GEL	35	100.00	0.000	NA
	P-LMA	35	100.00	0.000	
SpO_2_5min	I-GEL	35	100.00	0.000	NA
	P-LMA	35	100.00	0.000	
SpO_2_10min	I-GEL	35	100.00	0.000	NA
	P-LMA	35	100.00	0.000	
SpO_2_15min	I-GEL	35	100.00	0.000	NA
	P-LMA	35	100.00	0.000	

*NA - Not Applicable.

Comparing the oxygen saturation in both the groups at corresponding timings showed that the standard deviation of both the groups at baseline, 1 minute, 5 minutes, 10minutes, 15 minutes after insertion of the device were zero, so the p value is not applicable.

POST EXTUBATION COUGH:

Table 15. Intergroup comparison of post extubation cough in response to insertion of the device.

			Post extubation cough		Total
			Yes	No	
Device	I-GEL	Count	0	35	35
		% within Device	0%	100.0%	100.0%
	P-LMA	Count	0	35	35
		% within Device	0%	100.0%	100.0%

Post extubation cough was not noted in any of the patient in both I-gel group and P-LMA groups.

LARYNGOSPASM:

Table 16. Intergroup comparison of laryngospasm in response to insertion of the device.

			Laryngospasm		Total
			Yes	No	
Device	I-GEL	Count	0	35	35
		% within Device	0%	100.0%	100.0%
	P-LMA	Count	0	35	35
		% within Device	0%	100.0%	100.0%

Laryngospasm was not noted in any of the patient in both I-gel and P-LMA groups.

NAUSEA / VOMITING:

Table 17. Intergroup comparison of nausea / vomiting in response to insertion of the device.

			Nausea / Vomiting		Total
			Yes	No	
Device	I-GEL	Count	0	35	35
		% within Device	0%	100.0%	100.0%
	P-LMA	Count	0	35	35
		% within Device	0%	100.0%	100.0%

Nausea / vomiting was not noted in any of the patient in both I-gel and P-LMA groups.

TRAUMA TO LIP / TEETH / PHARYNX:

Table 18. Intergroup comparison of trauma to lip / teeth / pharynx in response to insertion of the device.

			Nausea / Vomiting		Total
			Yes	No	
Device	I-GEL	Count	0	35	35
		% within Device	0%	100.0%	100.0%
	P-LMA	Count	0	35	35
		% within Device	0%	100.0%	100.0%

Trauma to lip / teeth / pharynx was not noted in any of the patient in both I-gel and P-LMA groups.

POST OPERATIVE SORE THROAT :

Table 19. Intergroup comparison of postoperative sore throat in response to insertion of the device.

			Sore throat		Total
			Yes	No	
Device	I-GEL	Count	1	34	35
		% within Device	2.9%	97.1%	100.0%
	P-LMA	Count	2	33	35
		% within Device	5.7%	94.3%	100.0%

p value = 1.000

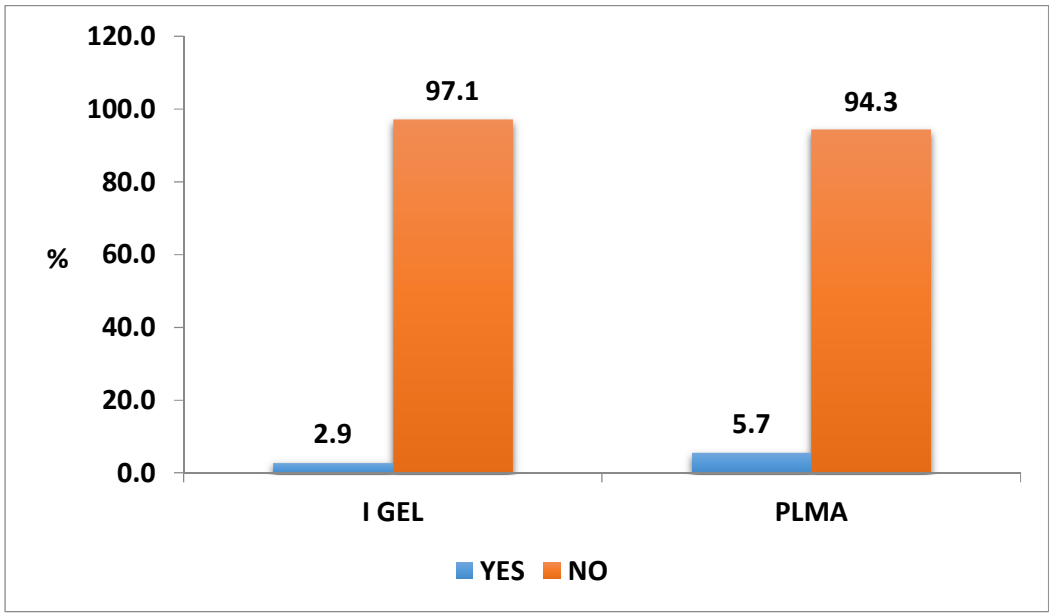

Chart13. Intergroup comparison of postoperative sore throat in response to insertion of the device.

Post operative sore throat was noted in 1 patient in I-gel group out of 35 and in 2 patients of P-LMA group out of 35. However the incidence was not statistically significant as p value was 1.000 (p value >0.05 non significant). The sore throat in all the cases were mild requiring no treatment.

DISCUSSION

Safe and efficacious airway management is one of the most important aspects of anaesthesia. Securing an airway and ventilation is a basic part of the management of all patients, regardless of whether the patient requires a short duration or day care surgery. Today, the LMA has come to be widely used as an alternative airway device during day care anaesthesia. The LMA has become an alternative to the facemask, as well as to endotracheal tube.

In this study, the safety and efficacy of the two supraglottic airway devices, namely, I-gel and proseal LMA had been compared. Seventy patients, scheduled for puerperal/laparoscopic sterilisation under general anaesthesia belonging to ASA class I and II were included in the study and were randomly divided into two groups with 35 patients in each group. In Group A (n=35), I-gel supraglottic airway device was used and in Group B (n=35) proseal laryngeal mask airway was used.

The I-gel and P-LMA both had drain tubes which permitted passage of a gastric tube and allowed the gastric contents to drain to the exterior. The I-gel does not have an inflatable cuff thereby avoiding the problems associated such as, increased cuff pressure above the recommended 60cm water either due to inflation with too much air or due to diffusion of nitrous oxide during the course of anaesthesia. The inflatable cuff also has the chances of malposition or get damaged after multiple uses, but before the recommended number of uses.

Both the devices were compared in relation to the time taken for insertion of device, number of insertion attempts, airway sealing pressure, ease of gastric tube

placement, hemodynamic changes after insertion, intraoperative and postoperative complications.

In our study, the mean time taken for insertion of I-gel was 12.40secs, which was shorter compared to P-LMA (mean insertion time for P-LMA was 14.23secs). This difference was statistically significant (p value = 0.000). This shorter time to insert could be attributed to the absence of an inflatable cuff in I-gel. This observation was similar to the results of Gurudas K et al[20], Anjan D et al[21], Gaurav C et al[22], Hayashi K et al[24] in their studies.

In our study, I-gel was inserted in first attempt in 97.1% of patients and in second attempt in 2.9% of patients whereas, P-LMA was inserted in first attempt only in 88.6% of patients and in second attempt in 11.4% of the patients.In these patients jaw thrust maneuver was applied during the second attempt and the device was inserted. But the difference was not significant statistically (p value = 0.356). This observation was similar to the results of Sai S et al[19] and Woo JJ et al[28] in their studies. Brimacome J et al[39] in his study had found insertion of P-LMA was difficult unless an introducer tool was used. Gasteiger L et al[30], in his studies, found that insertion of both the devices were similarly easy using a guided technique.

In our study, the mean airway sealing pressure of I-gel was 23.40 cmsH2O, which was lesser compared to P-LMA (mean airway sealing pressure for P-LMA was 28.29 cmsH2O). This difference was statistically significant (p value = 0.000).This observation was similar to the results of Gaurav Cet al[22], Singh I et al[31] in their studies.Gasteiger L et al[25] in his study found similar oropharyngeal sealing pressures with both I-gel and P-LMA. On the contrary, I-gel was found to have

higher airway sealing pressure compared to P-LMA by SubroM etal[26]in his study, which was statistically significant.

In our study, we found the passage of gastric tube with adequate lubrication through the drain tube of both I-gel and P-LMA to be easy. In both the groups, gastric tube was inserted in first attempt in 97.1% of patients and in second attempt in 2.9% of patients. But the difference was not significant statistically (p value 1.00). This observation was similar to the results of Sai S et al[19], Gurudas K et al[20] in their studies. On the contrary, Gaurav C et al[22] had found gastric tube insertion to be easier in I-gel than P-LMA, which was statistically significant.

In our study, we found the mean heart rate was found to be statistically significant in baseline, 1 minute, 5 minutes, 10 minutes and 15 minutes after insertion of the device (p value <0.05). We also found the changes in mean systolic blood pressure were not significant (p value > 0.05) in baseline, 1 minute, 5 minutes, 10 minutes and 15 minutes after insertion of the devices, but changes in mean diastolic bloodpressure were significant (p < 0.05) at 1 minute, 5 minutes, 10 minutes and 15 minutes after insertion of the device except for mean diastolic blood pressure at baseline, where it was not significant (p value > 0.05). We also found the changes in mean arterial blood pressure werenot significant (p value > 0.05) in baseline, 1 minute and 5 minutes after insertion of the devices, but changes in mean systolic pressure were significant (p value < 0.05) 10 minutes and 15 minutes after insertion of the device. Also there was no change in oxygen saturation in both the groups from baseline till 15 minutes after insertion of the device.

Though hemodynamic changes with respect to heart rate, arterial pressures and oxygen saturation were statistically significant, the changes in absolute values in hemodynamics between these two groups were not clinically significant. During insertion of the device,pressor response may be produced by passage of the device through oral and pharyngeal spaces and the pressure produced by the device in pharyngeal and laryngeal spaces. Anjan D et al[21] found that hemodynamics was lesser altered with I-gel than P-LMA, which were statistically significant.

In our study, no incidence of complications like post extubation cough, laryngospasm, nausea / vomiting, trauma to lip / teeth / pharynx was noted. Post operative sore throat was noted in 2.9% of patients in I-gel group, whereas sore throat was noted in 5.7 % of patients in P-LMA group. Since the p value was 1.000, this difference was found to be not significant statistically.The sore throats in all the cases of both the groups were mild, requiring no treatment. Factors like multiple insertions of the device, the pressure exerted by the cuff against the pharyngeal mucosa, the cuff volumes and pressures could have contributed to the development of postoperative sore throat in both the groups.

The results of our study on the complications induced by the device, had been supported by other studies done by Sai S et al[19], who showed that there was no significant complications in the first 12 hrs postoperatively and Singh I et al[31],whose study showed that the incidences of airway trauma and blood staining were statistically insignificant. Gurudas K et al[20] showed that the incidence of postoperative sore throat were insignificant in both the study groups. On the contrary, the study concluded by Gaurav C etal[22] and Shi YB et al[23] showed lesser complications with I-gel group than P-LMA group.

LIMITATIONS OF THE STUDY

- Small sample size which consisted of adult population only.
- Proper positioning of the supraglottic airway device was not confirmed with fiberoscope.
- Cost effectiveness of the reusable against the single use device was not taken into consideration.
- The Anaesthesiologist performing the insertion of the device could not be blinded.

SUMMARY

A study entitled "COMPARISON OF CLINICAL PERFORMANCE OF TWO SUPRAGLOTTIC AIRWAY DEVICES, I-GEL WITH PROSEAL - LARYNGEAL MASK AIRWAY (LMA) IN PATIENTS UNDERGOING ELECTIVE SURGERIES – A PROSPECTIVE RANDOMIZED STUDY" was conducted in department of Anaesthesiology, Thanjavur medical college, Thanjavur.

After approval from the Ethics Committee, informed consent was obtained from 70 patients (ASA grade Iand II) scheduled for puerperal/laparoscopic sterilisation under general anaesthesia. Patients under this study were randomized to one of the two groups, with 35 patients in each group.

Group A: I-GEL (N = 35)

Group B: PROSEAL LARYNGEAL MASK AIRWAY (N = 35).

Pre-anaesthetic evaluation was done on the day before surgery. All patients were pre-medicated with Tablet Alprazolam 0.5mg and Tablet Ranitidine 150 mg on the night before the day of surgery. All patients were kept nil per oral 6 hours prior to surgery. On arrival to operation theatre, an 18 Gauge intravenous cannula was placed. The patient was connected to a monitor, which recorded heart rate, non invasive blood pressure including systolic, diastolic and mean arterial pressures, continuous ECG monitoring and oxygen saturation.

All patients were pre-oxygenated with 100% Oxygen for 3 minutes with facemask. Anaesthesia was induced with injection Propofol 2-2.5mg/kg and Fentanyl 1.5 µg/kg. After checking for ventilation ,neuromuscular blockade was achieved with injection Atracurium 0.5mg/kg. Anaesthetic depth was deepened with 1% Sevoflurane in oxygen using bag and mask ventilation for 3 minutes after which patient was kept in 'sniffing the morning air' position and the allotted device of appropriate size was inserted. The device was connected to breathing circuit and patient was ventilated through ventilator with appropriate settings. Maintenance was achieved by Nitrous oxide and Oxygen in 2:1 ratio with 1% Sevoflurane and intermittent doses of intravenous Atracurium 0.1mg/kg.

Insertion time was recorded by an independent observer and defined as time interval between picking up the device and securing an effective airway.An effective airway was judged by bilateral symmetrical chest movements, a square wave capnography trace, lack of gastric insufflation and absence of leak.. The number of insertion attempts was recorded. The cuff of proseal LMA was inflated with air and maintained at a pressure of less than 60 cms of water..

The airway sealing pressure was determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 litres per minute and recording the airway pressure at which equilibrium was achieved. At this time, gas leakage was determined at the mouth by the audible leak or by detection of an audible noise using a stethoscope placed just lateral to thyroid cartilage.

A lubricated gastric tube of appropriate size was placed into the stomach through the gastric channel. The ease of placement of gastric tube was recorded.

Intra-operative heart rate (HR) in beats per minute, non-invasive blood pressure (NIBP) in mm of Hg and oxygen saturation (SpO2) in percentage was recorded at 1 minute ,5 minutes, 10 minutes and 15 minutes after insertion of device. At the end of surgical procedure anaesthesia was discontinued, patient was reversed with standard doses of injection Neostigmine 0.05mg/kg with Glycopyrollate 0.01mg/kg. Post extubation cough, laryngospasm, blood staining of the device and tongue, lip and dental trauma were recorded. Regurgitation of gastric contents was also assessed. Post operative sore throat was assessed in post-anaesthesia care unit.

Table 20. Overall comparison of both the groups based on the results obtained.

	Group A (I-gel)	**Group B (P-LMA)**
Mean age (in years)	28.89	28.80
Mean weight (in kgs)	58.51	53.51
ASA physical status - I / II	33 / 2	32 / 3
Mean time taken for insertion (in seconds)	12.40	14.23
Number of attempts taken for insertion of device - first / second	34 / 1	31 / 4
Airway sealing pressure (cms H2O)	23.40	28.29
Number of attempts taken to insert gastric tube - first / second	34 / 1	34 / 1
Post extubation cough	0	0
Laryngospasm	0	0
Trauma to lip/teeth/pharynx	0	0
Nausea/vomiting	0	0
Postoperative sore throat	1	2

The mean time taken for insertion of the device was lower in I-gel group, compared to P-LMA, which was statistically significant (p value = 0.000).

I-gel was successfully inserted in 34 patients in first attempt, whereas P-LMA was successful in 31 patients in first attempt. But this difference was not statistically significant (p value = 0.356).

The mean airway sealing pressure of I-gel was 23.40 cmsH2O, which was smaller compared to mean airway sealing pressure of P-LMA which was 28.29 cmsH2O. This difference was statistically significant (p value = 0.000).

Gastric tube insertion was successful in first attempt in 34 patients of both I-gel and P-LMA groups. But this difference was not statistically significant (p value = 1.00).

The mean heart rate was found to be statistically significant in baseline, 1 minute, 5 minutes, 10 minutes and 15 minutes after insertion of the device (p value <0.05). We also found the changes in mean systolic blood pressure were not significant (p value > 0.05) in baseline, 1 minute, 5 minutes, 10 minutes and 15 minutes after insertion of the devices, but changes in mean diastolic blood pressure were significant (p < 0.05) at 1 minute, 5 minutes, 10 minutes and 15 minutes after insertion of the device except for mean diastolic blood pressure at baseline, where it was not significant (p value > 0.05). We also found the changes in mean arterial blood pressure were not significant (p value > 0.05) in baseline, 1 minute and 5 minutes after insertion of the devices, but changes in mean systolic pressure were significant (p value < 0.05) 10 minutes and 15 minutes after insertion of the device. Also there was no change in oxygen saturation in both the groups from baseline till 15 minutes after insertion of the device.

Though hemodynamic changes with respect to heart rate, arterial pressures and oxygen saturation were statistically significant, the changes in absolute values in hemodynamics between these two groups were not clinically significant. During insertion of the device, pressor response may be produced by passage of the device

through oral and pharyngeal spaces and the pressure produced by the device in pharyngeal and laryngeal spaces.

In our study, no incidence of complications like post extubation cough, laryngospasm, nausea / vomiting, trauma to lip / teeth / pharynx was noted. Post operative sore throat was noted in 2.9% of patients in I-gel group, whereas sore throat was noted in 5.7 % of patients in P-LMA group. Since the p value was 1.000, this difference was found to be not significant statistically.The sore throats in all the cases of both the groups were mild, requiring no treatment. Factors like multiple insertions of the device, the pressure exerted by the cuff against the pharyngeal mucosa, the cuff volumes and pressures could have contributed to the development of postoperative sore throat in both the groups.

CONCLUSIONS

From this study we conclude that both I-gel and proseal LMA are safe and effective supraglottic airway devices, whereas I-gel is relatively easier and faster to insert with lesser hemodynamic changes compared to proseal LMA. Insertion is smooth without any trauma to anatomical structures in both I-gel and proseal LMA. Though I-gel produces lesser airway sealing pressure compared to proseal LMA, still I-gel is safer alternate airway device in positive pressure ventilation. The gastric access is easy and atraumatic, with majority being inserted in the first attempt in both the groups.Patients in both the groups were relatively free of postextubation cough, laryngospasm, nausea and vomiting and postoperative sore throat.

Both I-gel and proseal LMA are safe and patient friendly tools in the hands of anaesthetists for surgeries under general anaesthesia with positive pressure ventilation.

RECOMMENDATIONS

1. I-gel is relatively easier and faster to insert compared to proseal LMA.
2. I-gel is a safer alternate airway device in positive pressure ventilation compared to proseal LMA.
3. Both I-gel and proseal LMA cause lesser intra operative and postoperative complications.
4. Both I-gel and proseal LMA are better alternatives to endotracheal tube in patients undergoing general anaesthesia with positive pressure ventilation.
5. Both I-gel and proseal LMA are safe and effective supraglottic airway devices.

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STUDY PROFORMA

"COMPARISON OF CLINICAL PERFORMANCE OF TWO SUPRAGLOTTIC AIRWAY DEVICES, I-GEL WITH PROSEAL - LARYNGEAL MASK AIRWAY (LMA) IN PATIENTS UNDERGOING ELECTIVE SURGERIES – A PROSPECTIVE RANDOMIZED STUDY ".

Group A: I-GEL (size:)

Group B: PROSEAL LMA (size:)

Name:

Age/Gender:

IP number/ Date of surgery:

ASA physical status

Weight:

Height:

Body Mass Index:

<u>Pre op examination:</u>

Pulse rate:

Blood pressure:

Cardiovascular system:

Respiratory system:

Airway:

Mouth opening (cms):

Mallampatti Grade:

Neck movements:

Duration of surgery:

Investigations:

Premedication:

OBSERVATIONS:

1) Insertion time:

2)Ease of insertion:

3) Number of device insertion attempts:

One	
Two	
Three	
Failure	

4)Gastric tube access: (Yes / No)

First attempt	
Second attempt	

5)Airway sealing pressure:

6)Intra-operative hemodynamics:

TIME	HEART RATE	NIBP			SpO2
		SBP	DBP	MAP	
Baseline					
1 min after insertion					
5 mins after insertion					
10mins after insertion					
15 mins after insertion					

7) Post-operative device related complications:

Post-extubationcough	yes	/	no
Laryngospasm	yes	/	no
Nausea/Vomiting	yes	/	no
Trauma to lip/teeth/pharynx	yes	/	no
Sore throat	yes	/	no

KEY TO MASTER CHART

AI	After insertion
F	Female
kg	Kilograms
cm H2O	Centimeter of water
Y	Yes
N	No
min	Minute

MASTER CHART

Serial No.	IP No.	Age (Years)	Sex	Weight (Kg)	ASA grade	Device	Size	Insertion time (Seconds)	Number of device insertion	Airway sealing pressure	Number of gastric tube attempts	HR Basal	HR 1 min AI	HR 5 min AI	HR 10 min AI	HR 15 min AI	SBP Basal	SBP 1 min AI	SBP 5 min AI	SBP 10 min AI	SBP 15 min AI
1	400976	31	F	64	2	I GEL	4	13	1	23	1	81	85	78	68	70	120	120	118	118	120
2	400072	25	F	57	1	PLMA	4	13	1	29	1	68	75	78	76	75	126	120	118	116	114
3	400111	28	F	61	1	I GEL	4	12	1	22	1	64	70	82	85	83	124	122	114	110	118
4	399818	30	F	55	1	I GEL	3	12	1	23	1	82	90	92	84	86	120	116	110	106	108
5	399870	31	F	39	1	PLMA	3	14	1	28	1	87	96	95	98	95	124	120	123	124	126
6	400025	30	F	55	1	I GEL	3	11	1	25	1	82	90	92	86	84	118	116	112	108	108
7	400392	32	F	55	1	PLMA	4	13	1	30	1	96	99	96	94	90	130	120	118	116	112
8	400282	29	F	63	1	I GEL	4	13	1	24	1	82	84	80	82	80	128	130	128	124	122
9	400304	28	F	49	1	I GEL	3	10	1	23	1	79	84	84	76	70	117	121	122	118	120
10	400166	27	F	65	1	PLMA	4	14	2	28	2	74	79	72	73	77	118	104	100	101	103
11	400040	25	F	64	1	PLMA	4	15	2	29	1	78	86	85	88	86	117	120	118	115	112
12	400171	28	F	62	1	I GEL	4	12	1	22	1	76	80	82	79	76	120	118	113	110	108
13	400266	28	F	63	1	I GEL	4	13	1	24	1	80	78	74	74	72	132	127	126	126	120
14	400208	27	F	40	1	PLMA	3	14	1	27	1	76	85	90	88	91	128	134	128	125	120
15	400195	32	F	58	1	I GEL	3	13	1	23	1	78	90	88	93	90	136	126	120	112	122
16	400470	30	F	48	2	PLMA	3	13	1	27	1	90	92	90	88	86	112	114	108	108	109
17	400301	28	F	62	1	I GEL	4	13	1	22	1	78	82	85	84	83	108	110	104	104	106
18	400421	29	F	61	1	I GEL	4	14	1	23	1	78	86	84	83	85	108	112	104	104	106
19	399922	29	F	43	1	PLMA	3	14	1	28	1	76	85	88	89	85	110	110	100	108	112
20	400327	27	F	58	2	PLMA	4	20	2	29	1	67	73	69	72	71	117	126	120	115	106
21	399721	30	F	62	1	I GEL	4	12	1	23	1	72	74	78	82	80	122	120	112	108	120
22	399457	26	F	45	1	PLMA	3	13	1	28	1	101	103	99	96	94	129	120	122	123	130
23	400083	27	F	50	1	I GEL	3	12	1	22	1	76	85	87	86	84	120	118	112	108	110